AMENDING EXECUTIVE ORDER 12866: GOOD GOVERNANCE OR REGULATORY USURPATION? PART I AND PART II

HEARINGS

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

ONE HUNDRED TENTH CONGRESS

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AMENDING EXECUTIVE ORDER 12866: GOOD GOVERNANCE OR REGULATORY USURPATION? PART I

TUESDAY, FEBRUARY 13, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 11:35 a.m., in Room 2141 of the Rayburn House Office Building, Hon. Brad Miller [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
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The Subcommittee on Investigations and Oversight

Hearing on:

"Amending Executive Order 12866: Good Governance or Regulatory Usurpation?"

2141 Rayburn House Office Building
Washington, D.C.

Tuesday, February 13, 2007
12:00 PM – 1:30 PM

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Rick Melberth
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OMB Watch, Director

William Kovacs
Vice President, Environment, Technology & Regulatory Affairs
U.S. Chamber of Commerce

HEARING CHARTER

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I

TUESDAY, FEBRUARY 13, 2007
12:00 P.M.–1:30 P.M.
2141 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Tuesday, February 13, 2007 the Subcommittee on Investigations and Oversight of the Committee on Science and Technology will hold a hearing to receive testimony regarding the President's recent amendment to Executive Order 12866. That order provides guidance to agencies for submitting proposed regulations to the Office of Management and Budget (OMB) for pre-approval.

The amendment (Executive Order 13422) expands this process by requiring agencies to submit proposed significant guidance documents for pre-approval. The Order also requires for the first time that agencies identify in writing the specific market failure or problem that warrants the proposed regulation or guidance; that a Presidential appointee in each agency be designated as regulatory policy officer and that officer must approve each regulatory undertaking by the agency.

The hearing will explore the consequences of Executive Order 12866, as it has been used by the Bush Administration, as well as the impact of this amendment to the order. Among the issues the Subcommittee will seek information on are:

1. What has been the record of OMB's use of Executive Order 12866 to date, with particular attention to its use under the Bush Administration?
2. How will the expansion of OMB's role impact the ability of agencies to follow the laws passed by Congress to protect public safety and health?
3. What are the practical implications of having a Presidential appointee at each agency act as a minder on what rule-making work can be started at an agency and what can leave the agency to go to OMB?

Witnesses

Sally Katzen: Adjunct Professor and Public Service Fellow at University of Michigan Law School: Former Director of OIRA during the Clinton Administration.

David Vladick: Professor of Law, Georgetown University Law Center.

Rick Melberth, Ph.D.: Director, Federal Regulatory Policy, OMB Watch

Bill Kovacs: Vice President for Environment, Technology, and Regulatory Affairs, U.S. Chamber of Commerce (minority witness).

Key Issues

Regulatory authority is the main tool Congress has used to charge Executive agencies with responsibilities to protect the environment, public health, the safety of the workplace, the use of public lands and a myriad of other good purposes. Congress obviously cannot pass a law, or amend statute, every time a new threat to air or health arises. Instead, Congress puts into place general purposes, general authority and a set of values that the agency should use in carrying out the law.

When the Office of Information and Regulatory Analysis (OIRA) injects itself into the regulatory process there can be a fine line between guaranteeing that a proposed regulation is convincingly demonstrated and efficient in its likely outcome and substituting the President's values and preferences for the goals and purposes Congress enacted in statute. This line can be crossed either in the guidance to agencies from OIRA or by the way OIRA conducts itself.

OIRA has quietly grown into the most powerful regulatory agency in Washington. The Reagan Administration used OIRA push further and further into the process of vetting regulations. A string of Executive Orders in the 1980s, many issued during David Stockman's tenure at OMB, forced agencies to let OIRA be a full partner—some thought dominant partner—in moving regulations forward. Several House Chairs fought a very bitter struggle to push OIRA back out of the business of interfering with the conduct of agencies as they carried out the law. That fight met only mixed success.

As discussed below, E.O. 12866 was a Clinton-era effort to retain Reagan-initiated White House oversight of agency regulatory processes that had been the product of Reagan initiatives, balanced against the recognition that agencies should have primacy in the regulatory process. The thrust of E.O. 12866 was to pare back the array of regulatory actions that would be swept up into OIRA's review (the estimate was that the annual number of regulations for review declined from 2000 to a mere 500 or so). Clinton's OIRA, while still assertive, was cognizant that it was ultimately the agencies that were charged by Congress with carrying out public purposes and OIRA's assertions of authority had to be tempered by that legal reality.

The Bush Administration has moved very aggressively to supplant the agencies' authority with a centralized command-and-control system whereby OIRA acts as a very stingy gatekeeper on what proposed regulations can see the light of day. In tone, OIRA has returned to the Reagan-era where OIRA uses its privileged position as "the President's voice" in regulatory matters, to push agencies into rethinking everything they are doing on regulation.

Critics of OIRA's role since 2001 describe a process whereby the values and judgments of OIRA's small staff (dominated by economists) trump the judgments of technical experts in the agencies and supplant the values in statute designed to guide agency regulatory activities. The cumulative effect of OIRA's behavior since 2001 has been to intimidate agencies into running away from pursuing their statutory responsibilities rather than get caught up in the political struggles associated with moving regulation forward. Supporters of this approach are happy to see some office moving to slow agency actions and argue that the net result of OIRA's actions is a more defensible regulation at the end of the day.

How does all this matter for science and the agencies under the Science Committee's jurisdiction?

Every year the Federal Government funds billions of dollars of research at the Environmental Protection Administration, the Department of Labor, the Department of Transportation, the Department of Agriculture, the Department of the Interior, the Department of Energy and the National Oceanic and Atmospheric Administration that contribute directly or indirectly to regulatory considerations. Even the National Institutes of Health and the National Science Foundation fund science that finds its way into regulatory proposals. Experts at agencies—often federal scientists—charged with regulatory responsibilities survey the relevant scientific literature to determine where there may be dangers to the public or the public interest. In determining the need for a regulation, the agency uses science funded with public dollars, as well as that from private sources, to make reasoned assessments of risks and propose responses. This is all to be done consistent with statutory responsibilities as established by Congress.

OIRA has been using its circulars to force agencies to analyze and reanalyze the information underlying and supporting proposed regulations. Now, with the amended Executive Order, OIRA is putting in place very clear economic criteria for regulation and guidance that may have nothing to do with the values established in statute. This effort is coming with no consultation or input from Congress. Further, by making the regulatory policy officer a more empowered gatekeeper, with political allegiance to the President, it raises the chances that the agencies themselves will find it hard during the Bush years to get regulatory proposals started or completed simply to submit them to OIRA for review. Congress did not empower agencies to protect public health and safety simply to then sit on its hands to see all Congress appropriates for regulatory-relevant science and the legal authority seated in agencies be trumped through a sweeping Executive Order.

Background

Brief History of OMB: What is now known as the Office of Management and Budget ("OMB") was originally created in the Budget and Accounting Act of 1921.[1] The Act created the Bureau of Budget ("BOB") in the Treasury Department. Congress created the BOB to unify the budget process and have the executive branch

[1] 42 Stat. 22, Ch. 18, Sec. 207. OMB currently resides at U.S.C. Title 31, Chapter 5 (31 U.S.C. Sec. 501).

send a single budget to Congress. Previously, the executive branch transmitted budgets to Congressional committees independently of one another, and the budget process was consequently highly fragmented. Created at the same time was the Congress's General Accounting Office (now the Government Accountability Office) to give Congress an ability to independently check the budgetary information from the Executive as well as to examine the way programs were being funded and managed.

In 1939, Congress moved the BOB from the Treasury Department to the Executive Office of the President.[2] FDR, largely through executive order, expanded BOB's functions to include broad management oversight of federal operations.

In 1970, BOB went through another major reorganization which saw it transformed into OMB.[3] At this time, the federal management oversight functions of OMB were expanded, and have continued to be expanded until the present day.

The next major change to OMB occurred with the 1980 *Paperwork Reduction Act.*[4] This act created the Office of Information and Regulatory Affairs ("OIRA") within OMB.[5] OIRA's original charge was primarily to reduce the Government paperwork burden on the public and to develop policies and standards with regard to information management. One focus of this was to eliminate duplicitous or unnecessary paperwork and information collections.

Other major laws affecting OMB are the *Congressional Budget Act of 1974,* and the *Budget Enforcement Act of 1990.* The Budget Enforcement Act expired in 2002.

OIRA and Executive Order 12866: The Office of Information and Regulatory Affairs ("OIRA") was created with the 1980 *Paperwork Reduction Act.*[6] Under the enabling act, OIRA was charged with reducing the Government paperwork burden on the public and developing policies and standards with regard to information management. Throughout the years, OIRA's functions have been expanded through legislation and executive action. The major surviving changes include the *Paperwork Reduction Act of 1995*[7] and Executive Order #12866 (1993). **In addition, during the current Bush Administration, OIRA has come to oversee implementation of the Data Access Law**[8] **and the Data Quality Law,**[9] **including the peer review practices of agencies.** The effect of these, and other changes to OIRA, has guaranteed that OIRA is the central player in the promulgation of virtually all federal regulations.

Executive Order 12866 requires the following from all agencies:

1. Assess the economic costs and benefits of all regulatory proposals;
2. Complete a Regulatory Impact Analysis (RIA) for all major rules (any rule that will have an impact of $100 million or more, or that OMB designates as major). The RIA must describe the costs and benefits of the proposed rule and alternative approaches, and then justify the chosen approach;
3. Submit all major proposed and final rules to OMB for review;
4. Wait until OMB reviews and approves the rule before publishing proposed and final rules;
5. Submit an annual plan to OMB to establish regulatory priorities and improve coordination of the Administration's regulatory program (this requirement also applies to independent agencies);
6. Periodically review existing rules.

Most of these requirements actually originated in earlier administrations (particularly the Reagan Administration). The initiatives of the Reagan years had turned OIRA into a kind of "gatekeeper" that stood between the agencies and putting regulations out for comment (or finalizing them). However, the Clinton Administration intended to set a different tone and, drawing on what they felt to be the best of the ideas of the Reagan years, drafted a new Executive Order to organize and guide the work of OIRA.

Sally Katzen, an attorney by training with experience in the Carter Administration's management system, took the lead in drafting E.O. 12866. That process involved comment and review from all the agencies, as well as participation by OMB General Counsel, White House Counsel and Domestic Policy Staff and even the President himself. What Katzen attempted to do has been described as the "hot tub

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[2] 53 Stat. 1423, Sec. 1.
[3] 84 Stat. 2085, Sec. 102(a), restated 88 Stat. 11, Sec. 1.
[4] 44 U.S.C. Chapter 35, P.L. 96–511, restated P.L. 104–13, 109 Stat. 163.
[5] 44 U.S.C. Sec. 3503.
[6] 44 U.S.C. Chapter 35, P.L. 96–511, restated P.L. 104–13, 109 Stat. 163.
[7] 44 U.S.C. Chapter 35, P.L. 104–13, 109 Stat. 163.
[8] P.L. 105–277, 112 Stat 2681.
[9] P.L. 106–554, Sec. 515, 114 Stat. 2763.

theory" of managing regulation. Rather than being a gatekeeper, OIRA would work with agencies to put out the best regulations possible. The economics of a proposal were important, but not to the exclusion of other values. Indeed, there was recognition that not everything valued by society could have a dollar value assigned to it. **In addition, some statutes require agencies to consider economic costs only in choosing among alternatives for achieving the goal of the regulation, not whether to issue the regulation or not.**

Clinton's approach changed regulatory oversight. First, it set up a 90-day period for OMB review of proposed rules, and created a mechanism for the timely resolution of disputes between OMB and agency heads. There would be no "paralysis by analysis" if these commitments were kept. Second, it created new public disclosure requirements which mandated that all documents exchanged between OMB and the agency during regulatory review be made available to the public at the conclusion of the rule-making. Lastly, the Order created a process for meetings between OMB officials and people outside the executive branch regarding pending reviews which attempted to shine a more public light on these types of meetings.

These aspects of E.O. 12866 made the OMB regulatory review process much more transparent and limited OMB's ability to "kill" agency rule-making by endless OMB review. The E.O. also focused OMB review to only include major rule-making instead of all rule-making, reducing the number of regulations reviewed each year from 2,200 under Reagan, to about 500 under Clinton.

Bush Amendments to E.O. 12866: The Bush Administration has amended this Executive Order two times. The first amendment in 2002 simply removed the Vice President from the process, replacing that office with that of the White House chief of staff. This second occasion for amendment has come with limited warning, little discussion and with much broader implications. The attached CRS report goes into detailed discussion of the major changes, and some of their implications. Below is a summary of the key observations.

1. Elevating "Market Failure":

First, the amendment establishes a new standard that must be met by any proposed guidance or regulation. Originally, the first principle guiding submissions to OIRA seeking approval of a proposed regulation was that "[e]ach agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem."

Under the amended language, "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of the problem, to enable assessment of whether any new regulation is warranted."

Critics of OIRA allege that this new standard of "market failure" supplants the values that exist in statute for regulatory action. They also worry that OIRA will use this standard to summarily dispense with proposals that they deem to be unconvincing in their articulation of a market failure. However, there is permissive language allowing for other kinds of analysis. The core question will rest on how OIRA applies this language in practice.

2. Presidential Appointees as Regulatory Policy Officers

The amendment directs that each agency shall name a regulatory policy officer who shall be a Presidential appointee. While regulatory policy officers had been required in the Executive Order as originally propounded in 1993, the notion that the officer must be a Presidential appointee takes the expert staff of agencies out of the picture. The language of the amendment charges this officer with being "involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order."

This political appointee appears to serve as a kind of gatekeeper's gatekeeper. The officer will compose an annual plan and "no rule-making shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office." Previously such officers were to be involved in the rule-making process and now they have total discretion over the initiation of work that could lead to a regulation. (CRS states that these Regulatory officers are largely drawn from political appointees already so this may not be a notable change; however, the source on that is OIRA and they do not keep a master list of these officers so it is hard to know how to evaluate this assertion.)

3. Aggregate Regulatory Costs and Benefits

The original of 12866 required a "summary of planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of anticipated costs and benefits." The amendment expands this requirement to direct that each agency provide the "best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities."

Critics allege that this will elevate cost-benefit analysis in the regulatory process. Cost-benefit analysis is a very controversial analytical tool in guiding regulatory behavior. While the call to make sure that the benefits of a regulation exceed its costs has a simple appeal, the reality is that many of the benefits regulations are designed to capture (the survival of a species, to protect the lives and health of citizens, the quality of the air or water) are impossible to accurately value. However, the costs of steps to implement a regulation are usually easy to specify with precision. The result is a process that tends to be very complete in its enumeration of costs and incomplete in its ability to set values on the benefits. Retrospective studies have found that costs used in estimating the costs of a regulation turn out to be overstated. And of course because you are using "dollars" to estimate costs, it provides the illusion of a precision that does not—perhaps cannot—exist.

Critics also view this as a potential first step towards a regulatory "budget" that could be used to stop future regulations based on some "capping" of that budget.

4. Review of Significant Guidance Documents

Under the amendment each agency is to provide OIRA with advance notice of all proposed significant guidance documents. OIRA may then decide which guidance it deems to be "significant" from its perspective and ask for the proposed guidance and a brief explanation of need. "The OIRA administrator shall notify the agency when additional consultation will be required before issuance of the significant guidance document."

There is no time limit on how long OIRA may take in moving on these guidance proposals.

The impact on agency conduct may be very, very significant and could potentially sweep up thousands of such proposals each year. Guidance is issued to communicate to an effected public how an agency intends to interpret or enforce statutory directions. The business community relies on guidance to ensure that conduct will comply with agency intentions for application of law.

Conclusion

While the language of the Amendment to Executive Order 12866 is alarming to many, the fundamental issue is how does OIRA intend to implement it? The reemergence of the "gatekeeper" approach to OIRA under President Bush—an event that has not so far received the kind of institutional push-back from Congress which that role drew in the 1980s—suggests that the rule as amended will be used very aggressively to stall agency action. But how OIRA intends to apply this language in practice is a subject worth some study.

Two other issues loom large from the Committee on Science and Technology's perspective. First, what will these changes imply for the science-based regulatory agencies? Will we increasingly find that the "science" that matters is no longer that of climate, biological or medical researchers, but narrow applications of cost-benefit analysis and market failure theory drawn from economics? Should the science committee, uniquely positioned to examine and evaluate research, undertake a more rigorous review of the validity and utility of these economic approaches to regulation?

Second, what does this new amendment imply for the institutional prerogatives of the legislative branch? Agencies exist in statute and are given mandates under the law. Should Congress passively accept an Executive Order that, just as an example, places Presidential appointees in a position where they can arbitrarily block career agency officials from carrying out the purposes of the law Congress charged them with?

The growth of power at the Office of Information and Regulatory Affairs has gone largely unexamined in recent years. This amendment invites Congress as a body, and many, many Committees that are affected, to undertake a vigorous and thorough review of the changes in that office since 2001.

Appendix:

Other Regulatory Tools that OMB has used to expand its Powers:

Data Quality: There were two recent acts of legislation that affected OMB's oversight of data. They are the Data Access Law and the Data Quality Law. Both of these laws were inserted into omnibus appropriations bills, and neither was fully debated in Congress.

The entire Data Access Law consists of the following short passage:

"Office of Management and Budget Salaries and Expenses

> . . .Provided further, That the Director of OMB amends Section———.36 of OMB Circular A–110 to require federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the *Freedom of Information Act:* Provided further, That if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable use fee equaling the incremental cost of obtaining the data. . ." [10]

The purpose of the law was to increase public access to data conducted with funding from federal grants. Another purpose of the law was to overturn Forsham v. Harris,[11] which stood for the principle that data generated by a privately controlled organization which received grant funds from a federal agency were not 'agency records' accessible under the *Freedom of Information Act.*

The *Data Quality Act* ("DQA"), was inserted into the FY 2001 *Consolidated Appropriations Act.*[12] The Data Quality Act instructed OMB to establish guidelines to federal agencies for "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." Through its guidelines,[13] OMB directed agencies to establish "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency." To date, there appears to have been over 100 DQA petitions filed with numerous federal agencies. OMB does not compile a list of DQA petitions, so ascertaining the exact number of petitions filed is cumbersome. OMB Watch (*www.ombwatch.org*) keeps track of the individual petitions filed at each agency, and maintains a comprehensive list of DQA petitions.

Two major questions concerning the DQA remain unresolved. The first is whether the DQA applies to agency rule-making. It is clear that the DQA applies to agency action outside the rule-making process (for instance, agency dissemination of information through websites). However, there is no guidance in the actual legislation as to the applicability of the DQA to rule-making. There appears to be a consensus position across the federal agencies that the DQA doesn't apply to rule-making, as the rule-making process already allows for public comment. Furthermore, the DQA contains no reference to the *Administrative Procedure Act.* Nevertheless, industry petitioners have successfully used the DQA petition process to influence agency rule-making. One instance involves the chemical atrizine. As a result of a DQA petition, the EPA included a sentence in a scientific assessment of the risks of atrazine that stated hormone disruption cannot be considered a "legitimate regulatory endpoint at this time." [14] Atrazine is banned in Europe precisely because of the evidence that it is an endocrine disruptor. By attacking the science underlying potential rule-making, the petitioners were able to avoid agency rule-making altogether.

Another major question concerning the DQA is whether DQA petitions are judicially reviewable. Thus far, the major case on the issue held that DQA petitions are not judicially reviewable.[15] However, further challenges in different circuits are planned, and the issue may not be fully settled. Judicial review of DQA petitions would cause massive delays to the petition process.

DQA Based Regulations: OIRA developed two important new regulations based on the *Data Quality Act:* OMB Peer Review Guidelines[16] and OMB Risk Assessment Bulletin (Proposed). OMB's Peer Review Guidelines dictate that "important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government." The guidelines apply to all "scientific infor-

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[10] P.L. 105–277, 112 Stat. 2681.
[11] 445 U.S. 169 (1980).
[12] P.L. 106–554, 114 Stat. 2763(A).
[13] 67 FR 8452 (2002).
[14] Data Quality Law is Nemesis of Regulation, *Washington Post,* August 16, 2004.
[15] Salt Institute v. Michael O. Leavitt, 440 F.3d 156 (2006).
[16] 70 FR 2664 (2005).

mation disseminations that contain findings or conclusions that represent the official position of one or more agencies of the Federal Government." OMB's guidelines establish minimum peer review standards for federal agencies. Varying requirements for peer review are established based on the potential influence of the scientific information, with "highly influential scientific assessments" receiving the strictest peer review requirements. OMB asserts its legal authority to impose the Peer Review Guidelines flows from the *Data Quality Act*'s direction to OMB to provide guidance for federal agencies for "ensuring and maximizing the quality, objectivity, utility and integrity of information" which is disseminated.

OIRA recently proposed a Risk Assessment Bulletin.[17] This has not yet been published in its final form. The Risk Assessment Bulletin establishes "quality standards for risk assessment disseminated by federal agencies." Much like the Peer Review Bulletin, the Risk Assessment guidelines have varying levels of quality standards. There is one set of standards for general risk assessments and another set of stricter standards for influential risk assessments. Influential risk assessment is defined as "a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." OMB again asserts legal authority to issue the bulletin arises from the *Data Quality Act.* This Risk Assessment proposal was soundly rejected by the National Academy of Sciences in their January review. That step seems to have killed the proposal.

Analysis

The effect of the *Data Quality Act,* Peer Review Bulletin and Risk Assessment Bulletin is to impose an additional layer of regulatory administration on agencies that, for the most part, already have strong internal guidelines (at least for peer review and risk assessment). The result of this will likely be greater delay in agency dissemination of information, and a chilling effect that might discourage agencies from attempting to disseminate information in the first place. The bulletins also represent another step in OMB's continuing effort to insert itself into agency affairs. In addition, the possibility remains that OMB will attempt to use its authority under the *Data Quality Act* to insert itself into the agency rule-making process. This could potentially reek havoc on the rule-making process, and create years of new legal challenges related to the rule-making process. Needless to say, that would cause significant slowdown of an already slow rule-making process.

[17] Notice of proposal at: 71 FR 2600. Text of the proposed bulletin is not published in the *Federal Register.*

Chairman MILLER. The Committee hearing will come to order. And good afternoon to all of you. I want to welcome all of you to this first hearing of the Investigations and Oversight Subcommittee of the Committee of Science and Technology for purposes of this hearing on the growing role of the Office of Information and Regulatory Affairs, OIRA.

Mr. Costello, who is not here, will serve as the Vice Chairman. There has not been an Investigations and Oversight Subcommittee of the Committee on Science and Technology for a dozen years, and I look forward to working with all of you, the Members who are not here, plus anyone out there as well, and working with all of you on a very active, very engaged subcommittee.

We will work to expose abuse of power, corruption, and waste. A great American political scientist, Woodrow Wilson, called that the informing power of Congress, and said that it was probably more important than Congress' legislative powers. The light we shine will often be unwelcome by those whose conduct we illuminate, but unflattering scrutiny from Congress should be a healthy deterrent to the abuse of power.

Today's hearing is part of our oversight duties, to consider broader public policy questions that need the attention of Congress. I have heard the phrase "it takes an act of Congress" my entire life, but it has taken on new meaning for me in these last four years that I have served in Congress. When Congress enacts legislation to protect public health, the environment, safety, civil rights, privacy, and on and on, Congress cannot possibly anticipate every circumstance that will arise, and Congress cannot possibly address every new circumstance by new legislation. So Congress has long delegated to federal agencies the power to enforce the laws that Congress passes, and to adopt regulations that address circumstances within the intended protection of the legislation, but not specifically addressed.

Federal agencies frequently rely on scientific research, whether applied or basic, to inform their decisions. Scientific research within the jurisdiction of the Committee on Science and Technology, research by NOAA, EPA, NIH, the Departments of Labor and Agriculture, is all properly part of rule-making decisions, as are the standards and guidelines work at NIST and the Department of Transportation. We spend billions on that research. We should certainly examine how it is used in rule-making.

Rule-making decisions should properly be based on expertise, but that does not mean that they are beyond challenge. The authority of federal agencies should not amount to government by Platonic guardians, experts better informed and wiser than we are, and untroubled by tawdry concerns of politics. Congress and the President should pay close attention when agencies act, and should pay close attention when agencies fail to act. And we should pay close attention to the reasons for agency action or inaction, to what extent is agency action or inaction based on considerations of scientific expertise such as environmental or public health consequences, and to what extent is agency action or inaction based on economic or political considerations.

When agencies act, they must explain their decisions and allow public participation in that decision, but are decisions not to act

being made in back rooms, based upon considerations that never would withstand public scrutiny? Does Executive Order 13422 create an almost insuperable bias in favor of agency inaction, even in the face of clear need for action and a clear statutory directive to act? Does the order shield decisions at agencies from the scrutiny that they should receive? Does the order shift to the President powers that the Framers of our Constitution intended be exercised by Congress?

I welcome the testimony of our distinguished panelists on those issues. I also look forward to working with our distinguished Ranking Member, James Sensenbrenner. Mr. Sensenbrenner is by far my senior in Congress. He has served for four years as Chairman of the Judiciary Committee—excuse me, of this committee, the Committee on Science, six years as Chairman of the Judiciary Committee, and I hope he does not feel that after having been star player in the big leagues, he has now been sent back to the minors.

[The prepared statement of Chairman Miller follows:]

PREPARED STATEMENT OF CHAIRMAN BRAD MILLER

I want to welcome all of you to this first hearing of the Investigations and Oversight Subcommittee of the Committee on Science and Technology. For purposes of this hearing on the growing role of the Office of Information and Regulatory Affairs (OIRA), Mr. Costello will serve as the Vice Chairman.

There has not been an Investigations and Oversight Subcommittee of the Science and Technology Committee for a dozen years, and I look forward to working with all of you on a very active, very engaged subcommittee.

We will work to expose abuse of power, corruption and waste. A great American political scientist, Woodrow Wilson, called that the "informing power" of Congress, and said that it was probably more important than Congress' legislative powers. The light we shine will often be unwelcome by those whose conduct we illuminate, but unflattering scrutiny from Congress should be a healthy deterrent to the abuse of power.

Today's hearing is part of our oversight duties, to consider broader public policy questions that need the attention of Congress.

I've heard the phrase "it takes an act of Congress" all of my life, but it has taken on new meaning for me in first four years of my service in Congress. When Congress enacts legislation—to protect public health, the environment, safety, civil rights, privacy, and on and on—Congress cannot possibly anticipate every circumstance that will arise, and Congress cannot possibly address every new circumstance by new legislation.

So Congress has long delegated to federal agencies the power to enforce the laws that Congress passes, and to adopt regulations that address circumstances within the intended protection of the legislation, but not specifically addressed.

Federal agencies frequently rely on scientific research, whether applied or basic, to inform their decisions. Scientific research within the jurisdiction of the Committee on Science and Technology, research by NOAA, EPA, NIH, the Departments of Labor and Agriculture, is properly part of rule-making decisions, as are the standards and guidelines work at NIST and the Department of Transportation. We spend billions on that research; we should certainly examine how it's used in rule-making.

Rule-making decisions should properly be based on expertise, but that does not mean those decisions are beyond challenge. The authority of federal agencies should not amount to government by Platonic guardians, experts better informed and wiser than we are and untroubled by tawdry political concerns. Congress and the President should pay close attention to when agencies act, and to when agencies fail to act, and we should pay close attention to the reasons for agency action or inaction.

To what extent is agency action or inaction based on considerations of scientific expertise, such as environmental or public health consequences, and to what extent is agency action or inaction based on economic or political considerations? When agencies act, they must explain their decisions and allow public participation in the decision. But are decisions not to act being made in back rooms, based upon considerations that would never withstand public scrutiny?

Does Executive Order 13422 create an almost insuperable bias in favor of agency inaction, even in the face of a clear need for action and a clear statutory directive to act? Does the Order shield decisions at agencies from the scrutiny they should receive? And does the Order shift to the President powers that the framers of our Constitution intended be exercised by Congress?

I welcome the testimony of our distinguished panelists on these issues.

I also look forward to working with our very distinguished Ranking Member, James Sensenbrenner. Mr. Sensenbrenner served for four years as Chairman of the Committee on Science, and for six years on the Judiciary Committee. I hope he does not feel that after being a star player in the big leagues, he has now been sent back to the minors.

We very much welcome his experience and his expertise.

And I now recognize Mr. Sensenbrenner for his opening remarks.

Mr. SENSENBRENNER. I thank the gentleman from North Carolina for his comments. I am not in the minor leagues. I have a little bit different role, and not only is this role to keep the agencies on their toes, but also, to keep the Chairman and the Majority on their toes as well.

So, I would like to welcome him to the Chair of the Subcommittee, and say that I am looking forward to working with him and looking forward to making him a better Chair during the next two years.

Chairman MILLER. Something for me to look forward to.

And I also want to announce the one baseball analogy is out of deference and respect to our immediate past Chairman, Mr. Sherry Boehlert, but it will be the policy of this committee going forward that the preferred sports analogy are analogies to college basketball.

Elections have consequences.

Mr. SENSENBRENNER. That is fine, because Wisconsin is ranked third in the country, sir.

May I have an opening statement now?

Chairman MILLER. Actually, that is in my remarks, and I now recognize Mr. Sensenbrenner for his opening remarks.

Mr. SENSENBRENNER. Although this is the first Investigations and Oversight Subcommittee hearing since 1995, the record of oversight under my chairmanship speaks for itself, from monitoring the status of the Spallation Neutron Source of the Department of Energy to evaluating the proposal to bring Russia into the International Space Station Program, the Science and Technology Committee's vigilant oversight produced better programs and policies, and I look forward to returning to this committee and continuing the same rigorous oversight.

Having been the Chair of two committees, I am uniquely aware of the topic before us, and I am glad to see that my colleagues on the Judiciary Committee have taken an interest as well, and their expertise is appreciated.

As for the Executive Order and the OMB Bulletin, I am inclined to think that the issues that will be brought up today have less to do with their implications and more to do with who issued them. While I do get concerned when any Administration, be it Republican or Democratic, asserts too much control over the regulatory process, it is important to note that organizing that process is not and should not be a partisan endeavor, and it certainly didn't start with the current President.

President Clinton, just like several Presidents before him, used the regulatory process to advance his own agenda in the waning years of his Presidency. Ultimately, these policies last only as long as the current Administration allows them to, and the best way to ensure that longevity is to include the legislative branch. To quote a recent article on the topic in *CQ Weekly:* "While executive power is mighty, it is also ephemeral." Most of the issues that the Executive Order and the OMB Bulletin address are simple clarifications of organizational changes that President Clinton's Executive Order 12866, and will ultimately help OMB better coordinate the regulatory process. None of the amendments call for additional hurdles to be overcome. They simply require the reporting of work that has already been done.

Additionally, none of the issues or changes are anything new. All of them have either been released for public comment, like the OMB Bulletin on guidance documents, or are clarifications to President Clinton's original Executive Order. For example, the OMB Bulletin was issued in draft form over a year ago. While 31 comments were received, only three or four were negative. It is also interesting to note that none of our witnesses here today chose to issue comments on that Bulletin, save Mr. Kovacs. But OMB will have an opportunity to defend their document at the next hearing before the Judiciary Committee, and I am told we will be inviting them back before us at a later time as well.

Right now, I am more concerned with the impact that these guidance documents and regulations have on the American economy, particularly small businesses that can't afford high priced counsels and lobbyists to monitor the thousands of guidance documents and rules agencies issue each year. The increased use of guidance documents by agencies to circumvent the regulatory process has been diligently documented. They often conflict with each other, and are not subject to public notice and comment, and rarely receive agency approval, not to mention OMB review.

While I am concerned about the impact that Presidential appointees may have on the regulatory process, just as in the issue of market failure, these issues have all been addressed previously by other Administrations as well. In reality, the EO and the OMB Bulletin simply formalize many of the principles derived under the previous Administrations.

That being said, as a part of this committee's day-to-day oversight, I will certainly follow how these changes are implemented to ensure that public health and safety is preserved, and that there is transparency and accountability in our regulatory process.

Thank you.

[The prepared statement of Mr. Sensenbrenner follows:]

PREPARED STATEMENT OF REPRESENTATIVE F. JAMES SENSENBRENNER, JR.

Although this is the first Investigation & Oversight hearing since 1995, the record of oversight under my Chairmanship speaks for itself. From monitoring the status of the Spallation Neutron Source at the Department of Energy to evaluating the proposal to bring Russia into the International Space Station Program, the Science and Technology Committee's vigilant oversight produced better programs and policies, and I look forward to returning to this committee and continuing the same rigorous oversight.

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my colleagues on the Judiciary Committee have taken an interest as well, as their expertise is certainly appreciated.

As for the Executive Order and the OMB Bulletin, I am inclined to think that the issues that will be brought up today have less to do with their policy implications, and more to do with *who* issued them. While I do get concerned when any Administration (be it Republican or Democratic) asserts too much control over the Regulatory Process, it is important to note that organizing that process is not a partisan endeavor, and it certainly didn't start with the current President.

President Clinton, just like several Presidents before him, used the regulatory process to advance his own agenda in the waning years of his Presidency. Ultimately, these policies last only as long as the current Administration allows them to, and the best way to ensure their longevity is to include the Legislative Branch. To quote a recent article on the topic in *CQ Weekly,* "while Executive power is mighty, it is also ephemeral."

Most of the issues that the E.O. and the OMB Bulletin address are simple clarifications and organizational changes to President Clinton's E.O. (12866) and will ultimately help OMB better coordinate the regulatory process. None of the amendments call for additional hurdles to be overcome; they simply require the reporting of work that has already been done. Additionally, none of these issues or changes are anything new—all of them have either been released for public comment (like the OMB *Bulletin on Guidance Documents*) or are clarifications to President Clinton's Executive Order.

For example, the OMB Bulletin was issued in draft form over a year ago. While 31 comments were received, only three or four were negative. But OMB will have an opportunity to defend their document at the next hearing before the Judiciary Committee, and I am told we will be inviting them back before us at a later time as well.

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While I am concerned about the impact that Presidential Appointees may have on the regulatory process, just as in the issue of Market Failure, these issues have all been addressed previously under other Administrations as well. In reality, the E.O. and the OMB Bulletin simply formalize many of the principles derived under those previous Administrations. That being said, as part of the Committee's day-to-day oversight, I will certainly follow how these changes are implemented to ensure that public health and safety is preserved, and that there is transparency and accountability in our regulatory process.

I look forward to our witnesses' testimony today.

Chairman MILLER. Thank you, Mr. Sensenbrenner.

[The prepared statement of Mr. Costello follows:]

PREPARED STATEMENT OF REPRESENTATIVE JERRY F. COSTELLO

Good afternoon. Thank you, Mr. Chairman, for calling this hearing to examine the consequences of President Bush's recent amendment to Executive Order 12866, which requires Federal Government agencies to submit any proposed regulations to the Office of Management and Budget (OMB) for pre-approval.

The Science and Technology Committee has the authority to examine and evaluate the validity and utility of economic approaches to regulation. Further, agencies exist in statute and are given mandates under the law issued by Congress. The amendment put in place by the Bush Administration goes one step further than the current process by requiring agencies to identify in writing the specific market failure or problem that warrants the proposed regulation or guidance. Therefore, I look forward to hearing the perspective of the witnesses as to how they perceive the Bush Administration will implement its new amendment to Executive Order 12866 and their assessment on how this will impact science-based regulatory agencies and public safety.

I welcome today's witnesses and look forward to their testimony.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF REPRESENTATIVE EDDIE BERNICE JOHNSON

Thank you, Mr. Chairman. The President amended a key executive order to tighten the president's grip on federal agencies that enforce health, safety and environmental protections.

This order gives the White House's Office of Information and Regulatory Affairs (OIRA) enhanced tools to oversee and interfere with federal regulations on everything from warning labels on medicines to safety standards for construction work sites.

Executive Order 12866 built on a Clinton-era executive order which authorized OIRA to use cost-benefit analysis and other market-based calculations to evaluate rules and regulations proposed by federal agencies.

The Executive Order now enables the Bush Administration to oversee not only regulations, but also guidance documents that agencies issue to inform the public about how rules will be enforced. OIRA can now examine all significant guidance.

The amended executive order also now lists the economic concept of market failure as a standard for reviewing a proposed rule.

The notion of the free market having the ability to eventually resolve public needs could become an expansive pretext for OIRA to dismiss crucial regulatory protections.

I welcome the witnesses who are here today, especially Sally Katzen, the creator and Former Director of OIRA under the Clinton Administration.

Thank you, Mr. Chairman. I yield back.

Chairman MILLER. I would now like to welcome our witnesses. Today, we are honored to have a very distinguished and knowledgeable panel of witnesses.

Ms. Sally Katzen, the former head of the Office of Information and Regulatory Affairs, again OIRA, in the Clinton Administration, and currently a professor at the University of Michigan Law School. She is a recognized expert in federal regulatory matters, and we are very pleased to have her here today.

Mr. David Vladeck is a Director of the Institute for Public Representation, and a professor at Georgetown University Law Center. He is also an expert in administrative and regulatory law, topics on which he writes and testifies frequently before Congress.

Dr. Rick Melberth is the Director of Federal Regulatory Policy for OMB Watch, which works to protect and improve the government's ability to develop and enforce safeguards for public health, safety, the environment, and civil rights.

And finally, Mr. Bill Kovacs is the Vice President for Environment, Technology, and Regulatory Affairs, the Regulatory Affairs Division for the United States Chamber of Commerce. That division is responsible for such significant issues, including the systematic application of sound science to the federal regulatory process.

Now, it is the custom of the Investigations and Oversight Subcommittee, well, going back a dozen years, when we last had one, it is the custom of the Investigations and Oversight Subcommittee, and it will be our custom going forward, we are establishing it now, to swear in our witnesses.

Do any of you have any objection to being sworn in? Okay. If not, then if you would please stand and raise your right hand.

[Witnesses sworn.]

Chairman MILLER. We will now hear the statements of the entire panel, beginning with Ms. Katzen. To the panel, please limit your remarks to five minutes. We do have written testimony from all of you.

After all the statements have been received, the oral statements, all Members will have five minutes to ask questions.

Ms. Katzen, I think we begin with you.

STATEMENT OF MS. SALLY KATZEN, ADJUNCT PROFESSOR AND PUBLIC INTEREST/PUBLIC SERVICE FELLOW, UNIVERSITY OF MICHIGAN LAW SCHOOL

Ms. KATZEN. Thank you very much, and thank you for inviting me to testify today.

During the last six years, there has been a slow but steady change in the process by which federal regulatory agencies develop and issue regulations, specifically in the balance of authority between those agencies and the Office of Management and Budget. With its most recent actions, the Bush Administration has taken yet another step restricting agency discretion and making it more difficult for the agencies to do the job that Congress has delegated to them.

As you mentioned in your introduction, I served as the Administrator of OIRA for over five years during the Clinton Administration, and was involved in the drafting and implementation of Executive Order 12866. I am a strong proponent of centralized review of agency rule-making, and have often spoken and written in support or defense of OIRA. I am also a strong proponent of regulations, believing that if carefully crafted, they can improve the quality of our lives, the performance of our economy, and our nation's well-being.

Why, then, am I so critical of the new Executive Order? I have prepared written testimony that provides extensive background and explanatory information. I would like to use my five minutes to emphasize several important points. First, the Bush Administration has taken many discrete steps to tighten, incrementally to be sure, but tighten nonetheless OMB control over the agencies. The information or data quality guidelines, the peer review guidelines, Circular A–4 for regulatory analyses, the Risk Assessment Bulletin, and now, the *Bulletin on Good Guidance Practices,* all of which are described in my written testimony.

Now, each step, standing on its own, can be justified or defended, and none, standing on its own, warrants the outrage that was directed at them by the critics of the Administration. At the same time, the cumulative effect has been overwhelming on the agencies, and there is a dramatically different dynamic between the agencies and the White House than there was at the end of the Clinton Administration.

In Executive Order 12866, President Clinton continued the practice of centralized review of rule-makings by OIRA, but at the same time, he reaffirmed the primacy of the agencies, which are the repositories of significant expertise and experience, and the entities to which Congress has delegated the authority to issue rules that have the force and effect of law. Today, those same agencies have at least one arm tied behind their backs, two ten pound bricks tied to their ankles, and they are set on an obstacle course to navigate before they can issue any regulations. Forgive me for mangling my metaphors, but the combination of all the multiple mandates that OMB has imposed on the agencies makes it so much more difficult for them to do their job. Oversight is one thing—I am talking of Presidential oversight—but burdening the agencies to slow them down, or destroy their morale, is something else.

Now, I have heard that there is nothing new in the Executive Order. It is all business as usual. It is simply what the Clinton Administration had done. That is not the case. This is a dramatically different environment, and a dramatically different thrust. And I can go into detail, if you would like, during questions.

It is also—the one explanation that was given when the Executive Order was issued, had to do with increasing transparency and producing better decisions. That simply is not credible. Look at the way it was done. There was no consultation or explanation. Look at the effect it has on the agencies, coming on the heels of the many mandates that OMB has imposed on them, and look at the message it sends. Regulations to protect the environment or to promote the health and safety of American people are disfavored. Let the market, not the government, do it.

Executive Order 12866, as originally drafted, was neutral as to process, even though President Clinton was highly supportive of regulations as part of the solution to serious problems plaguing our society. The Executive Order was not skewed to achieve a pro-regulatory result. It was not a codification of a pro-regulatory philosophy or ideology. It was, on its face and by intent, a charter for good government, without any predetermination of outcomes. Simply stated, the agencies' regulations would be debated on the merits, not preordained by the process through which they were developed and issued.

In light of the actions taken over the last six years by the Bush Administration, that is no longer the case. With Executive Order 12866, as amended, each step in the process of extending Presidential control over the agencies has placed a thumb on the scale. By now, we have a whole fist influencing the outcome.

Thank you so much for holding this hearing. It is important for Congress to let the executive know that it takes these matters seriously and is deeply concerned about the implications of their recent actions on the integrity of the administrative process.

[The prepared statement of Ms. Katzen follows:]

PREPARED STATEMENT OF SALLY KATZEN

Chairman Miller and Members of the Subcommittee. Thank you for inviting me to testify today on a subject that is vitally important to the American people. During the last six years, there has been a slow but steady change in the process by which regulations are developed and issued—specifically, in the balance of authority between the federal regulatory agencies and the Office of Management and Budget. With its most recent actions, the Bush Administration has again restricted agency discretion and made it more difficult for them to do the job that Congress has delegated to the federal agencies. It is therefore important that this subcommittee consider the reasons for these changes and the implications of these changes for administrative law and regulatory practice.

I served as the Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) for the first five years of the Clinton Administration, then as the Deputy Assistant to the President for Economic Policy and Deputy Director of the National Economic Council, and then as the Deputy Director for Management of OMB. I am a proponent of centralized review of agency rule-making, and I was personally involved in the drafting and implementation of Executive Order 12866. I have remained active in the area of administrative law generally and rule-making in particular. Since leaving government service in January 2001, I have taught Administrative Law and related subjects at the University of Michigan Law School, George Mason University Law School, and the University of Pennsylvania Law School, and I have also taught American Government seminars to undergraduates at Smith College, Johns Hopkins University,

and the University of Michigan in Washington Program. I frequently speak and have written articles for scholarly publications on these issues.

On January 18, 2007, the Bush Administration released two documents. One was expected; the other was not. I can understand why OMB issued a "Final Bulletin for Good Guidance Practices." While I disagree with several of the choices made, I recognize that a case can be made that there is a need for such a Bulletin. On the other hand, there is no apparent need for Executive Order 13422, further amending Executive Order 12866. Regrettably, none of the plausible explanations for its issuance is at all convincing. As I will discuss below, there are at least three aspects of the new Executive Order that warrant attention: 1) the way it was done—without any consultation or explanation; 2) the context in which it was done—coming on the heels of OMB's imposing multiple mandates/requirements on the agencies when they are developing regulations; and 3) the effect it will have and the message it sends to the agencies—it will be even more difficult for agencies to do their jobs because regulations are disfavored in this Administration.

To put the most recent Executive Order in perspective, a little history may be helpful. The first steps towards centralized review of rule-making were taken in the 1970's by Presidents Nixon, Ford and Carter, each of whom had an ad hoc process for selectively reviewing agency rule-makings: President Nixon's was called the Quality of Life Review; President Ford's was focused on the agency's Inflationary Impact Analysis that accompanied the proposed regulation; and President Carter's was through the Regulatory Analysis Review Group. Those rule-makings that were considered significant were reviewed by an inter-agency group, which then contributed their critiques (often strongly influenced by economists) to the rule-making record.

In 1981, President Reagan took a significant additional step in issuing Executive Order 12291. That Order formalized a process that called for the review of all Executive Branch agency rule-makings—at the initial and the final stages—under specified standards for approval. The Office that President Reagan chose to conduct the review was the Office of Information and Regulatory Affairs (OIRA), established by the Congress for other purposes under the *Paperwork Reduction Act of 1980.* Unless OIRA approved the draft notice of proposed rule-making and the draft final rule, the agency could not issue its regulation.

Executive Order 12291 was highly controversial, provoking three principal complaints. One was that the Executive Order was unabashedly intended to bring about regulatory *relief*—not reform—relief for the business community from the burdens of regulation. Second, the Order placed enormous reliance on (and reflected unequivocal faith in) cost/benefit analysis, with an emphasis on the cost side of the equation. Third, the process was, by design, not transparent; indeed, the mantra was "leave no fingerprints," with the result that disfavored regulations were sent to OMB and disappeared into a big black hole. The critics of Executive Order 12291, including Members of Congress, expressed serious and deep concerns about the Executive Order, raising separation of powers arguments, the perceived bias against regulations, and the lack of openness and accountability of the process.

When President Clinton took office and I was confirmed by the Senate as the Administrator of OIRA, my first assignment was to evaluate Executive Order 12291 in light of the 12 years of experience under Presidents Reagan and Bush, and help draft a new Executive Order that would preserve the strengths of the previous Executive Order but correct the flaws that had made the process so controversial. President Clinton would retain centralized review of Executive Branch agency rule-makings, but the *development* and the *tone* of the Executive Order he would sign (Executive order 12866) was to be very different.

I was told that Executive Order 12291 was drafted in the White House (Boyden Gray and Jim Miller take credit for the document) and presented, after President Reagan had signed it, as a fait accomplis to the agencies. The protests from the agencies were declared moot. We took a different route, consulting and sharing drafts with the agencies, public interest groups, industry groups, Congressional staffers, and State and local government representatives. When all their comments were considered and changes made to the working draft, we again consulted and shared our new drafts with all the groups, and again took comments. More changes were made, and where comments were not accepted, we explained the basis for our decisions.

The tenor of Executive Order 12866 was also quite different from Executive Order 12291. As noted above, Executive Order 12866 retained centralized review of rule-makings, but also reaffirmed the primacy of the agencies to which Congress had delegated the authority to regulate. (Preamble) Among other things, Executive Order 12866 limited OIRA review to "significant regulations"—those with a likely substantial effect on the economy, on the environment, on public health or safety, etc., or

those raising novel policy issues (Section 6(b)(1))—leaving to the agencies the responsibility for carrying out the principles of the Executive Order on the vast majority (roughly 85 percent) of their regulations.

Executive Order 12866 continued to require agencies to assess the consequences of their proposals and to quantify and monetize both the costs and the benefits to the extent feasible. (Section 1(a)) But it explicitly recognized that some costs and some benefits cannot be quantified or monetized but are "nevertheless essential to consider." (Section 1(a)) I believe it was Einstein who had a sign in his office at Princeton to the effect that "not everything that can be counted counts, and not everything that counts can be counted."

While Executive Order 12291 required agencies to set their regulatory priorities "taking into account the conditions of the particular industries affected by the regulations [and] the condition of the national economy" (Section 2 (e)), Executive Order 12866 instructed agencies to consider "the degree and nature of the risks posed by various substances and activities within its jurisdiction" (Section 1(b)(4)), and it added to the list of relevant considerations for determining if a proposed regulation qualified as "significant" not only an adverse effect on the economy or a sector of the economy, but also "productivity, competition, jobs, the environment, public health or safety or State, local, or tribal governments or communities." (Section 3(f))

There were other significant differences between Executive Order 12291 and Executive Order 12866, including those relating to the timeliness of review and the transparency of the process, but for present purposes, the key to the difference was that President Clinton was focused on a process for better decision-making and hence better decisions and not a codification of a regulatory philosophy or ideology. Centralized review was seen as a valid exercise of presidential authority, facilitating political accountability (the President takes the credit and gets the blame for what his agencies decide) and to enhance regulatory efficacy (that is, decisions that take into account the multitude of disciplines and the multitude of perspectives that can and should be brought to bear in solving problems in our complex and interdependent society). But whatever one's view of centralized review of agency rulemakings, Executive Order 12866 was—on its face and by intent—a charter for good government, without any predetermination of outcomes.

The neutrality of the process was essential. President Clinton viewed regulations as perhaps the "single most critical. . .vehicle to achieve his domestic policy goals" (Kagan, 114 *Harv. L. Rev.* 2245, 2281–82 ((2001)), and he spoke often of the salutary effects of regulations on the Nation's quality of life and how regulations were part of the solution to perceived problems. But the Executive Order was not skewed to achieve a pro-regulatory result. The regulations would be debated on their merits, not preordained by the process through which they were developed and issued.

When George W. Bush became President in January 2001, his philosophy was decidedly anti-regulatory. I know that his advisors considered whether to change Executive Order 12866 and they concluded that it was not necessary to accomplish their agenda. Indeed, President Bush's OMB Director instructed the agencies to scrupulously adhere to the principles and procedures of Executive Order 12866 and its implementing guidelines. (OMB M–01–23, June 19, 2001) The only changes to the Executive Order came two years into President Bush's first term, and the changes were limited to transferring the roles assigned to the Vice President to the Chief of Staff or the OMB Director. (Executive Order 13258)

Almost five years later, President Bush signed Executive Order 13422, further amending Executive Order 12866. So far as I am aware, there was no consultation and no explanation of the problems under the existing Executive Order that prompted these amendments, or whether the amendments would have a salutary effect on whatever problems existed, or whether the amendments would have unintended consequences that should be considered. Press statements issued after the fact do not make for good government.

Second, the new Executive Order comes in the course of a steady and unwavering effort to consolidate authority in OMB and further restrict agency autonomy and discretion. On February 22, 2002, OMB issued its Information Quality Act (IQA) Guidelines. (67 *Fed. Reg.* 8452). The IQA itself was three paragraphs attached to a more than 700-page Treasury and General Government Appropriations Act for Fiscal Year 2001, with no hearings, no Floor debate and no committee reports. Its objective was "to ensure the quality, objectivity, utility and integrity of information disseminated to the public." OMB took up the assignment with a vigor and determination that was remarkable. OMB's government-wide guidelines created a new construct: now, there would be "information" and "influential information" and different (more stringent standards) would apply to the higher tiers. OMB also required the agencies to issues their own guidelines (subject to OMB approval); establish administrative mechanisms allowing people or entities to seek the correction of

information they believe does not comply with these guidelines; and report periodically to OMB on the number and nature of these complaints. The U.S. Chamber of Commerce thought this "would have a revolutionary impact on the regulatory process"—keeping the agencies from relying on data that industry thought was questionable.

Then came OMB's Proposed Draft Peer Review Standards for Regulatory Science (August. 29, 2003), in which OMB attempted to establish uniform government-wide standards for peer review of scientific information used in the regulatory process. Peer review is generally considered the gold standard for scientists. Yet leading scientific organizations were highly critical of what OMB was trying to do and how it was doing it, and they were joined by citizen advocacy groups and former government officials. They argued that the proposed standards were unduly prescriptive, unbalanced (in favor of industry), and introduced a new layer of OMB review of scientific or technical studies used in developing regulations. The reaction was so strong and so adverse that OMB substantially revised its draft Bulletin to make it appreciably less prescriptive and restrictive, and in fact OMB resubmitted it in draft form for further comments before finalizing the revised Bulletin.

On March 2, 2004, OMB replaced a 1996 "best practices" memorandum with Circular A–4, setting forth instructions for the federal agencies to follow in developing the regulatory analyses that accompany significant draft notices of proposed rulemaking and draft final rules. The Circular, almost 50-pages single spaced, includes a detailed discussion of the dos and don'ts of virtually every aspect of the documentation that is needed to justify a regulatory proposal. While the term "guidance" is used, agencies that depart from the terms of the Circular do so at their peril (or more precisely, at the peril of their regulatory proposal).

Then came the OMB Proposed Risk Assessment Bulletin (January 9, 2006), providing technical guidance for risk assessments produced by the Federal Government. There were six standards specified for all risk assessments and a seventh standard, consisting of five parts, for risk assessments related to regulatory analysis. In addition, using the terminology from the IQA Guidance, OMB laid out special standards for "Influential Risk Assessments" relating to reproducibility, comparisons with other results, presentation of numerical estimates, characterizing uncertainty, characterizing results, characterizing variability, characterizing human health effects, discussing scientific literature and addressing significant comments. Agency comments raised a number of very specific problems and such general concerns as that OMB was inappropriately intervening into the scientific underpinnings of regulatory proposals. OMB asked the National Academies of Scientists (NAS) to comment on the draft Bulletin. The NAS panel (on which I served) found the Bulletin "fundamentally flawed" and recommended that it be withdrawn.

Then, on January 18, 2007, OMB issued its final Bulletin on "Agency Good Guidance Practices." Agencies are increasingly using guidance documents to inform the public and to provide direction to their staff regarding agency policy on the interpretation or enforcement of their regulations. While guidance documents—by definition—do not have the force and effect of law, this trend has sparked concern by commentators, including scholars and the courts. In response, the Bulletin sets forth the policies and procedures agencies must follow for the "development, issuance, and use" of such documents. It calls for internal agency review and increased public participation—all to the good. In addition, however, the Bulletin also imposes specified "standard elements" for significant guidance documents; provides instructions as to the organization of agency websites containing significant guidance documents; requires agencies to develop procedures (and designate an agency official/office) so that the public can complain about significant guidance documents and seek their modification or rescission; and extends OIRA review to include significant guidance documents. I do not believe it is an overstatement to say that the effect of the Bulletin is to convert significant guidance documents into legislative rules, subject to all the requirements of Section 553 of the Administrative Procedure Act, even though the terms of that Section explicitly exempt guidance documents from its scope. To the extent that the Bulletin makes the issuance of guidance documents much more burdensome and time consuming for the agencies, it will undoubtedly result in a decrease of their use. That may well have unintended unfortunate consequences, because regulated entities often ask for and appreciate receiving clarification of their responsibilities under the law, as well as protection from haphazard enforcement of the law, by agency staff.

This is quite a record. While each step can be justified as helping to produce better regulatory decisions, the cumulative effect is overwhelming. Requirements are piled on requirements, which are piled on requirements that the agencies must satisfy before they can issue regulations (and now, significant guidance documents) that Congress authorized (indeed, often instructed) them to issue. And OMB has not

requested, nor has the Congress in recent years appropriated, additional resources for the agencies to carry out OMB's ever increasing demands. As agencies must do more with less, the result is that fewer regulations can be issued—which is exactly what the business community has been calling on this Administration to do.

It is in this context that Executive Order 13422, further amending Executive Order 12866, is released. Until the Bulletin on guidance documents, OIRA extended its influence throughout the Executive Branch without any amendments to Executive Order 12866. As discussed above, OMB issued Circulars and Bulletins covering a wide variety of subjects, virtually all of which were quite prescriptive (and often quite burdensome) in nature. OMB Circulars and Bulletins do not have the same status as an Executive Order, but they are treated as if they did by the federal agencies. Why then did OMB draft and the President sign Executive Order 13422?

One indication of a possible answer is that while Executive Order 13422 in effect codifies the Bulletin on guidance documents, it does not pick up and codify the earlier pronouncements on data quality, peer review, regulatory impact analyses, or even risk assessment principles. It may be that it was thought necessary to amend Executive Order 12866 for guidance documents because Executive Order 12866 was written to apply only where the agencies undertook regulatory actions that had the force and effect of law. But it is unlikely that the agencies would balk at submitting significant guidance documents to OIRA if there were an OMB Bulletin instructing them to do so, and since neither Executive Orders nor Circulars or Bulletins are judicially reviewable, it is also unlikely that anyone could successfully challenge in court an agency's decision to submit a significant guidance document to OIRA.

Perhaps more revealing of the reason(s) for Executive Order 13422 is that it is not limited to guidance documents. Consider the other amendments included in the new Executive Order. First, Executive Order 12866 had established as the first principle of regulation that:

> Each agency shall identify the problem that it intends to address (including, where applicable, the failure of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem"

Executive Order 13422 amends Executive Order 12866 to state instead:

> Each agency shall identify *in writing the specific market failure* (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, *to enable assessment of whether any new regulation is warranted.*

By giving special emphasis to market failures as the source of a problem warranting a new regulation, the Administration is saying that not all problems are equally deserving of attention; those caused by market failures are in a favored class and possibly the only class warranting new regulations. This could be read as a throw back to the "market-can-cure-almost-anything" approach, which is the litany of opponents of regulation; in fact, history has proven them wrong—there are many areas of our society where there are serious social or economic problems—e.g., civil rights—that are not caused by market failures and that can be ameliorated by regulation.

Second, the new Executive Order amends Section 4 of Executive Order 12866, which relates to the regulatory planning process and specifically references the Unified Regulatory Agenda prepared annually to inform the public about the various proposals under consideration at the agencies. The original Executive Order instructed each agency to also prepare a Regulatory Plan that identifies the most important regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year. Section 4, unlike the rest of the Executive Order, applies not only to Executive Branch agencies, but also to independent regulatory commissions, such as the Securities and Exchange Commission, the Federal Communications Commission, the Federal Trade Commission, and the Federal Reserve Board. It is not without significance that the new Executive Order uses Section 4 to impose an additional restraint on the agencies:

> Unless specifically authorized by the head of the agency, no rule-making shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office. . .

This language should be read in conjunction with an amendment to Section 6(a)(2) that specifies that the agency's Regulatory Policy Officer must be "one of the agency's Presidential Appointees." Executive Order 12866 had provided that the agency head was to designate the agency's Regulatory Policy Officer, with the only condition that the designee was to report to the agency head. The original Executive

Order further provided that the Regulatory Policy Officer was to "be involved at every stage of the regulatory process. . ."—in other words, a hands-on job. Now, there is an explicit politicalization of the process; a "sign-off," not a hands-on, assignment; and, most significantly, no accountability. The newly appointed officer is not required to be subject to Senate confirmation, nor is the person required to report to a Senate-confirmed appointee.

The other changes to Section 4 are also troubling. As amended, the agencies must now include with the Regulatory Plan the:

> agency's best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year. . .

Very few would dispute that the Regulatory Plan has been notoriously unreliable as an indicator of what an agency is likely to accomplish in any given timeframe; it is not unusual for regulations that are not included in the Plan to be issued should circumstances warrant, nor is it unusual for regulations included in the Plan with specific dates for various milestones to languish year after year without getting any closer to final form.

In any event, the requirement to aggregate the costs and benefits of all the regulations included in the Plan for that year is very curious. We know that costs and benefits can be estimated (at least within a range) at the notice stage because the agency will have settled on one or more options for its proposal. But to try to estimate either costs or benefits at the notice of inquiry stage or before the agency has made even tentative decisions is like trying to price a new house before there is even an option on the land and before there are any architect's plans. The numbers may be interesting, but hardly realistic, and to aggregate such numbers would likely do little to inform the public but could do much to inflame the opponents of regulation. This would not be the first time that large numbers that have virtually no relation to reality have driven the debate on regulation—e.g., the $1.1 trillion estimate of the annual costs of regulations that is frequently cited by opponents of regulation, even though every objective critique of the study that produced that number concludes that it not only overstates, but in fact grossly distorts, the truth about the costs of regulation. The only other plausible explanation for this amendment to the Executive Order it that it is the first step toward implementing a regulatory budget. In my view, the concept of a regulatory budget is deeply flawed, but it should be debated on the merits and not come in through the back door of an Executive Order designed for other purposes.

There is also a gratuitous poke at the agencies in the amendment to Section 4(C). The original Executive Order instructed the agencies to provide a "summary of the legal basis" for each action in the Regulatory Plan, "including whether any aspect of the action is required by statute or court order." The new amendment adds to the previous language the clause, "and specific citation to such statute, order or other legal authority." It may appear to be trivial to add this requirement, but by the same token, why is it necessary to impose such a requirement?

As noted above, I am not aware of any consultation about either the merits of any of the amendments or the perception that may attach to the cumulative effect of those amendments. Therefore, I do not know whether the agencies have, for example, been proposing regulations based on problems caused by something other than market failure which OMB does not consider an appropriate basis for a regulation; whether senior civil servants at the agencies have been sending proposed regulations to OMB that run contrary to the wishes of the political appointees at those agencies; or whether agencies have been misrepresenting what applicable statutes or court orders require.

If not, then there is little, if any, need for these amendments, other than to send a signal that the bar is being raised; that OMB is deciding the rules of the road; and that those rules are cast so as to increase the I's that must be dotted and the T's that must be crossed. In other words, the message is that agencies should not be doing the job that Congress has delegated to them. This is not a neutral process. If the Bush Administration does not like some or all agency proposed regulations, they can debate them on the merits. But the Executive Order should not become a codification of an anti-regulatory manifesto. This is not good government.

BIOGRAPHY FOR SALLY KATZEN

Since leaving government service in January 2001, she has been teaching both graduate students (University of Pennsylvania Law School in Spring '03; Johns Hopkins University in Fall '03, 04, University of Michigan Law School in Spring '04, Fall '05, Spring '06); George Mason University Law School, Spring and Fall '06) and undergraduates (at Smith College in Fall '01–'04; Johns Hopkins University in

Spring '02, '06; University of Michigan in Washington Program '05–'07). She served almost eight years in the Clinton Administration, first as Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB), then Deputy Assistant to the President for Economic Policy and Deputy Director of the National Economic Council in the White House, and then as the Deputy Director for Management at OMB. Before joining the Clinton Administration, Ms. Katzen was a partner in the Washington, DC law firm of Wilmer, Cutler & Pickering, specializing in regulatory and legislative matters. While in private practice, Ms. Katzen was an adjunct Professor at the Georgetown Law Center and served in various leadership roles in the American Bar Association (including Chair of the Section on Administrative Law and Regulatory Practice and two terms as DC Delegate to the House of Delegates of the ABA), as well as President of the Federal Communications Bar Association and President of the Women's Legal Defense Fund. She graduated magna cum laude from Smith College and magna cum laude from the University of Michigan Law School, where she was the first woman Editor in Chief of the *Law Review*. Following graduation from law school, she clerked for Judge J. Skelly Wright of the United States Court of Appeals for the District of Columbia Circuit. She also served in the Carter Administration for two years as the General Counsel of the Council on Wage and Price Stability in the Executive Office of the President.

Chairman MILLER. Thank you, Ms. Katzen. Mr. Vladeck.

STATEMENT OF MR. DAVID C. VLADECK, DIRECTOR, INSTITUTE FOR PUBLIC REPRESENTATION; ASSOCIATE PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER

Mr. VLADECK. Mr. Chairman, Mr. Sensenbrenner, thank you very much for inviting me here to testify before you today. I have submitted a detailed testimony outlining my major concerns with the new Executive Order, so I would like to use my five minutes to outline some of my most pressing concerns.

Let me begin with the bad news. The bad news is this: our regulatory process, and particularly, our health and science agencies, have been stretched to the breaking point. Agency budgets have been slashed, agency staffing levels have been cut to the bone, agency scientists have been demoralized by the blatant politicization of science, and not surprisingly, our agencies are fraying at the seams. It now takes OSHA a decade, a decade to issue standards to protect workers from occupational safety and health threats. The FDA, long the gold standard of our health and safety agencies, has experienced substantial regulatory failure. Defective medical devices, unsafe drugs, slip by the FDA and onto our markets.

We are now reaping what we have sown: under-resourced, underfunded, over-politicized agencies that can't do their job of protecting us, but these are the very agencies on which we depend to ensure that the food we eat is pure, the drugs we take are safe and effective, that the air we breathe is clean, and that our workplaces are not unreasonably dangerous.

Now, this is an Executive Order, and that means something. It is not simply a trivial statement of business as usual. Presidents use Executive Orders to mark important and dramatic steps, in terms of the way they organize the executive branch, and Executive Order 13422 is no different. It takes a number of steps that are problematic, and which Congress ought to take a very careful look at.

The first problem with the Executive Order that I see is that it usurps Congressional authority by directing agencies to justify regulatory action on the basis of market failure. And make no mis-

take, an agency, particularly if it is developing a regulation or guidance that OIRA deems significant, is going to have to do business with market failure. To be sure, there is an escape valve left in the Executive Order, but that escape valve is operative at OIRA's insistence, not the agency's, and so agencies, if they want to get their rules approved, if they want to go ahead with guidance, they are going to have to at least do business with OIRA on market failure bases.

The problem with this, of course is that, as Sally has just said, agencies have been given just an enormous number of analytic requirements that they have to navigate through in order to take regulatory action. Now, not simply binding regulatory action, but non-binding regulatory action. The executive branch seems to think that there is no limit to the number of analytical requirements that they can impose on the process. This process is already broken, and putting another straw on the camel's back is going to further undermine the ability of agencies to deliver the protection that Congress has decreed they deliver to us.

But the second problem—the expansion of OIRA's authority to guidance documents—makes no sense. Guidance documents, by their nature, are non-binding. The courts have been very clear in holding that a guidance document does not impose a binding requirement on a regulated industry. There is—there are arguments to be made about whether centralized review is a good idea or not. I disagree with my colleague Sally. I have always thought centralized review was bad, whether practiced by Republicans or Democrats, Mr. Sensenbrenner, but this is a completely unwarranted step, and oddly, a step that is going to hurt regulated business.

Mr. Sensenbrenner, you talked about small business. Small businesses need guidance from agencies about how to comply with federal mandates. Now, if they pick up a phone and call a regulatory officer at the FDA, for example, they are going to have to say, wait, I've got to do a market failure analysis before I can give you guidance? That kind of interaction is covered by this Executive Order. You are handcuffing the ability of our agencies to interact with the people they regulate, and interposing OIRA between them is not sound government policy.

The last point I want to make is this. I am very troubled by, and I would urge Congress to take a hard look at this, the Executive Order requiring a Presidential appointee to run the regulatory offices at the agencies. If you look and here—I hate to do this, because I have such respect for Mr. Copeland, but if you—and I disagree with him on this point—if you look at the way the agencies structure their regulatory compliance. In many agencies, particularly at the sub-cabinet level, the regulatory officers are political, but not Presidential appointees, but they are experts in regulation. They know the details, the arcane aspects of our regulatory process that now is all-enveloping.

To force the agency to find another employee, a Presidentially-appointed person, who may or may not be subject to Senate confirmation, is bad policy, and it is a threat to Congress, because when you give an agency authority to exercise regulatory power, you delegate that authority not to the agency, the statute doesn't read: "We ask the Department of Transportation to do something."

You tell the Secretary of Transportation to do it. Why? Because that person is accountable to you as well as the President.

I am fearful that this Executive Order seeks to end-run that kind of accountability that Congress has always demanded.

I see my time is up. Thank you very much.

[The prepared statement of Mr. Vladeck follows:]

PREPARED STATEMENT OF DAVID C. VLADECK

Mr. Chairman and Members of the Science and Technology Committee, thank you for inviting me to be here today to share with you my views about the January 18, 2007 revisions to Executive Order 12866, which are set forth in Executive Order 13422, 72 *Fed. Reg.* 2763 (January 23, 2007). I am the Director of the Institute for Public Representation and an Associate Professor of Law at Georgetown University Law Center. Prior to joining Georgetown's law faculty, I spent nearly thirty years at Public Citizen Litigation Group, serving as its director from 1992 through 2002. I have practiced extensively in the area of administrative law, served as a Public Member of the Administrative Conference of the United States, the Chair of the D.C. Bar Association's Section on Administrative Law, on the Council of the American Bar Association's Section on Administrative Law and Agency Practice, testified on many occasions before congressional committees on administrative law issues—including issues concerning the constitutionality and wisdom of centralized regulatory review—and I write in the field of administrative law. I also serve as a Scholar with the Center for Progressive Reform.

My testimony today will explain why Executive Order 13422 represents an important chapter in the Executive Branch's longstanding effort to wrest control over administrative agencies from Congress, and certainly the most important measure taken by President Bush. To put the new Order in context, I will begin by briefly describing the problems brought about by Executive Order 12866 and its predecessor, Executive Order 12291, and explain why centralized regulatory review has seriously impaired the ability of federal agencies to provide needed safeguards to the American people.

I will then turn to Executive Order 13422 and address why it marks a further and substantial erosion of Congress' role in the administrative process and deals a body blow to the ability of our agencies to do their jobs. Here I make a number of points about Executive Order 13422:

- **The Executive Order Usurps Congressional Authority By Directing Agencies to Justify Regulatory Actions on the Basis of Market Failure.** Under our system of separated powers, it is Congress, not the Executive, that sets the substantive standards that guide agencies in the performance of their delegated tasks. Executive Order 13422 disrespects this structural limit in the Constitution. It requires agencies, as a precondition to taking any regulatory action at all, to justify their proposed action on the basis of "market failure." And "significant" agency guidance may not be issued until the agency obtains clearance from the Office or Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB). The "market failure" super-mandate appears nowhere in statute. It is not in keeping with the decisional criteria that Congress has established, and it cannot be reconciled with the dominant thrust of the health and safety statutes, which are designed to prevent deaths and injuries by avoiding market failure, rather than waiting until it is too late and market failure is evident.
- **The Executive Order Unwisely Expands OIRA's Authority to Guidance Documents.** Whatever the wisdom of centralized OIRA review of binding agency rules, the same arguments do not extend to centralized review of non-binding agency guidance. Hundreds of guidance documents are issued each year, often in response to emergencies or other time-sensitive developments. Requiring agencies to stop dead in their tracks to justify the provision of guidance on "market failure" grounds cannot be defended on policy grounds; nor can giving OIRA the authority to meddle in the substance of significant agency guidance.
- **The Executive Order Resurrects the Discredited Concept of a Regulatory Budget.** Amended section 4(c)(1)(B) forbids any agency—even the so-called "independent" agencies—from commencing any rule-making unless the agency's regulatory plan sets forth, among other things, "the agency's best estimate of the combined aggregated costs and benefits of all its regulations planned for that calendar year." These estimates give OIRA the ability to effectively cap the amount of compliance costs an agency may impose in a calendar year, a power OIRA has long

coveted. Nothing in the statutes Congress has enacted give OIRA the right to ration the protection to be provided to the American people through regulation.

- **The Executive Order Further Politicizes the Regulatory Process.** Executive Order 13422 requires each agency "to designate one of the agency's Presidential Appointees" to serve as the agency's regulatory policy officer. At the same time, the Order greatly expands the duties of the policy officer, providing that, "[u]nless specifically authorized by the head of the agency, no rule-making shall commence nor be included on the [agency's annual regulatory] Plan without the approval" of the policy officer. Nothing in the Order suggests that the political appointee must also be subject to Senate confirmation. This is a troubling, and no doubt deliberate, omission. The statutes Congress enacts to delegate power to agencies designate the agency head—and not a subordinate—as the decision-maker. Congress does this to ensure that decisions are made by an official accountable to Congress as well as the President. The amended Executive Order undermines Congress' designation of the agency head as the decision-maker by requiring that a political employee—accountable to the President but not necessarily to Congress—be given control over an agency's regulatory output. That, to me, is quite a disturbing development and one that should not be accomplished by Executive fiat, but, if at all, by legislation.

BACKGROUND

To understand the significance of Executive Order 13422, it is useful to quickly sketch the development of the Executive Order on regulatory review and what it requires.[1] Although all Presidents since President Ford have employed some form of centralized review of agency regulations, systematic, wholesale review of regulations did not begin until the Reagan Administration. Just a month after his inauguration, President Reagan issued Executive Order 12291, which required agencies to prepare detailed Regulatory Impact Analyses specifying the costs and benefits of all proposed "major" rules. The Order provided that, unless otherwise forbidden by law, an agency could not undertake rule-making unless "the potential benefits to society. . .outweigh the costs," and the agency selected the regulatory option "involving the least net cost to society."[2] The Order further required agencies to submit drafts of all proposed and final rules to OIRA before publication in the *Federal Register,* and publication could not proceed without OIRA's approval.

From the outset, Congress was troubled by the dominant and often obstructionist role OIRA played in rule-makings. OIRA delayed and weakened rules, met in secret with industry representatives, overrode agency determinations on complex matters of science, and otherwise thwarted the ability of the regulatory agencies to do their jobs.[3] During 1982–83, the House held no fewer than seven hearings to examine health and safety rules seriously delayed or weakened by OIRA.[4] And when the first challenge to the constitutionality of OIRA's meddling in agency rule-making came before an appellate court, the Chairmen of the five House Committees having jurisdiction over regulatory agencies filed a brief setting forth a blistering critique of OIRA review. Here is just a brief sampling of what the five Chairmen said:

> The amici Congressmen object to the systematic usurpation of legislative power by OMB pursuant to Executive Order 12291 *
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> * * Executive Order 12291 is the cornerstone of a steadily growing Presidential apparatus, the effect of which is to contravene explicit Congressional delegations of authority, to subvert meaningful public participation in and judicial review of federal regulations, and to impose substantive standards on decision-makers foreign to the statutes they administer. Unless it is checked, the program embodied in Executive Order 12291 will fundamentally damage the administrative process by which our laws are implemented, the legislative system

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[1] See generally Curtis W. Copeland, *CRS Report for Congress: Changes to the OMB Regulatory Review Process by Executive Order 13422,* at 2–3 (Feb. 5, 2007) (hereinafter "CRS Report").

[2] Exec. Order 12291, §§ 1(b), 7(g)(2); 3 C.F.R. 127 (1981), *reprinted in* 5 U.S.C. § 601, at 431 (1982).

[3] See generally Morton Rosenberg, Beyond the Limits of Executive Power: Presidential Control of Agency Rule-making Under Executive Order 12291, 80 *Mich. L. Rev.* 193 (1981); David C. Vladeck, Unreasonable Delay, Unreasonable Intervention: The Battle to Force Regulation of Ethylene Oxide, in Peter L. Strauss, Ed., *Administrative Law Stories* (Foundation Press 2006).

[4] See, e.g., *OMB Control of OSHA Rule-making,* Hearings before the Subcomm. on Manpower of the House Comm. on Gov't. Operations, 97th Cong., 2d Sess. (1982); *Infant Formula: The Present Danger,* Hearings before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 97th Cong., 2d Sess. (1982); *EPA: Investigations of Superfund and Agency Abuses (Part 3),* Hearings before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 97th Cong., 1st Sess. (1981).

by which our laws are enacted and monitored, and the separation of powers upon which our system of government rests.[5]

In 1993, shortly after taking office, President Clinton issued Executive Order 12866 to make a number of significant modifications to the Reagan Executive Order. In my view, the most important was to inject transparency into the OIRA review process.[6] The Clinton Order cut back on the number of "significant" agency rules reviewed by OIRA. It also required OIRA, as a general rule, to complete its review of proposed and final rules within ninety calendar days. And it required all agencies, including the so-called independents, to prepare an annual regulatory plan outlining all important regulatory actions the agency intended to take during that fiscal year. The plans had to be personally approved by agency heads.[7]

Even with the adjustments made by President Clinton, centralized review of the regulatory output of administrative agencies has never accomplished its objective of making our regulatory agencies better serve the public. Indeed, the ultimate irony is that if OIRA's review process was subjected to cost-benefit analysis, OIRA review would flunk. The amount of time, energy, money and, at times, political capital that goes into satisfying OIRA that a rule is worthy of publication dwarfs any conceivable benefits that flow from the process. We have now had a twenty-five year experiment with centralized review. Judged by any legitimate measure, it is time to declare the experiment a failure and move on. There are several reasons for my conclusion.

To begin with, centralized review is a one-way ratchet. OIRA presses agencies to do less to protect the public health, not more. Agencies do not complain that OIRA is forcing them to do more; they complain that OIRA is forcing them to weaken required protections.

OIRA's insistence that agencies do less, not more, stems from its singular focus on "least net cost options"—or, in other words, minimizing regulatory compliance costs. The Executive Order requires agencies to perform cost-benefit analysis, which many experts claim is inherently anti-regulatory.[8] My own litigation experience bears this out. I have represented workers and labor unions in litigation to force OSHA to protect workers from exposure to many highly toxic and carcinogenic chemicals, including ethylene oxide, cadmium, hexavalent chromium, formaldehyde and benzene.[9] In each case, OIRA was an obstacle to the agency's action. Part of OIRA's objection was its unwillingness to place any value on important health benefits of regulation—including avoided cancers, miscarriages, genetic damage that might cause infertility or birth defects, and kidney failure that might require dialysis or transplant—because they were too difficult to quantify. While the anticipated *costs* of regulation are generally easier to estimate (and overestimate), the *benefits* of regulation are notoriously difficult to quantify and are often downplayed or ignored by OIRA. And when OIRA does place a value on a benefit or regulation, it discounts those values heavily. Indeed, lives that are going to be lost twenty or thirty years down the road are devalued to the point of insignificance.

There is also the problem of competence. The next car you buy is almost certain to have a gauge on the dashboard to warn you when the car's tires are under-inflated. Congress required this safety feature after a spate of deadly roll-over crashes caused, in part, by under-inflated tires. The National Highway Traffic Safety Administration (NHTSA) proposed to require automobile manufacturers to install devices that would detect under-inflated tires in virtually all cases. OIRA insisted that NHTSA permit the installation not only of the device NHTSA's engineers determined was best, but also a far less effective (and less expensive) device favored by

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[5] Brief of John Dingell, Chair, House Energy and Commerce Committee, Peter Rodino, Chair, House Judiciary Committee, Jack Brooks, House Government Operations Committee, Augustus Hawkins, Chair, House Education and Labor Committee, and William D. Ford, Chair, House Post Office and Civil Service Committee, in *Public Citizen Health Research Group v. Tyson,* 796 F.2d 1479 (D.C. Cir. 1986).

[6] See Executive Order 12866, §§ 6(b) & (c); 58 Fed. Reg. 51,735 (1993).

[7] Harvard Law School Dean Elena Kagan has traced the development of the Clinton Executive Order in *Presidential Administration,* 114 *Harv. L. Rev.* 2245 (2001).

[8] See generally Frank Ackerman & Lisa Heinzerling, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (New Press 2004); Lisa Heinzerling, *Regulatory Costs of Mythic Proportion,* 107 *Yale L. J.* 1981 (1998).

[9] See, e.g., *Public Citizen Health Research Group v. Auchter,* 702 F.2d 1150 (D.C. Cir. 1983); 796 F.2d 1479 (D.C. Cir. 1986); 823 F.2d 626 (D.C. Cir. 1987) (decisions requiring OSHA to regulate ethylene oxide, a potent carcinogen and teratogen); *International Chemical Workers Union v. Pendergrass,* 958 F.2d 1144 (D.C. Cir. 1992); 830 F.2d 369 (D.C. Cir. 1987) (decisions compelling OSHA to regulate cadmium, a potent lung carcinogen); *Public Citizen Health Research Group v. Chao,* 314 F.3d 143 (3d Cir. 2002); 145 F.3d 120 (3d Cir. 1998) (decisions forcing OSHA to regulate hexavalent chromium, a potent lung and liver carcinogen); *UAW v. Pendergrass,* 878 F.2d 389 (D.C. Cir. 1989) (decision requiring OSHA to regulate formaldehyde).

the auto industry. Not surprisingly, NHTSA did what it was told. Empowering OIRA economists to second-guess highly technical judgments made by expert agencies is not good government. Ultimately, Public Citizen succeeded in getting a court to overturn the OIRA-dictated decision and direct NHTSA to require the installation of the more effective devices. But the introduction of this important, life-saving device was delayed because of OIRA's interference. This is hardly an isolated case.[10]

There is also enormous delay built into OIRA review which has resulted in the ossification of the regulatory process. The regulatory process is so overlain with procedural and regulatory requirements that agencies cannot get their work done in a reasonable time. It now takes OSHA a decade to promulgate a standard to protect workers from exposure to toxic substances.[11] While the rule-making process grinds glacially ahead, workers are exposed to unreasonable risks to their health and well-being. Other agencies face comparable delays. And much of the delay can be traced back to all of the requirements imposed by the Executive Order.

These problems are all well-known, and in fairness to the Clinton Administration, and my friend and co-panelist Sally Katzen, some efforts were undertaken to address them. But Executive Order 13422 makes a bad situation worse. Let me now address how Executive Order 13422 is a significant step backwards, and an affront to the power of Congress.

PRINCIPAL DEFECTS IN EXECUTIVE ORDER 13422

As noted above, although packaged as an innocuous and minor amendment to Executive Order 12866, the new Executive Order takes a number of dramatic and important steps in the wrong direction. The principal ones are these:

1. The Amendments Impose a "Super-Mandate" That Supersedes Legislation and Needlessly Burdens Already Overburdened Agencies.

The amendments to the Executive Order give OIRA a powerful new tool to block agency action. Before moving forward with *any* regulatory action, an agency must determine in writing that the action the agency wants to take or guidance the agency wants to provide is warranted by "market failure." There are several problems with the imposition of this mandate.

First, it serves to undermine the criteria that Congress has established for agency action. Under our system of separated powers, it is Congress, not the Executive, that sets the substantive standards that guide agencies in the performance of their delegated tasks. Executive Order 13422 is at odds with this rule. No statute requires an agency to consider "market failure" as a precondition to taking action. Nor is the consideration of market failure in keeping with the decisional criteria that Congress has established—which generally focus on health, safety, and the protection of our environment and natural resources. Indeed, the elevation of "market failure" as a key determinant for agency action cannot be reconciled with the fundamental goal of the health and safety statutes, which is to prevent deaths and injuries by avoiding market failure, rather than waiting until it is too late and market failure is evident.[12]

Second, the mandate adds a burden that will sap the resources of already overburdened agencies. To take any regulatory action at all, agencies will have to consider "market failure" and write a justification of the action it seeks to take on that

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[10] OIRA's meddling in the tire pressure rule is recounted in *Public Citizen v. Mineta,* 340 F.3d 39 (2d Cir. 2003). For a more recent, but equally troubling, example of OIRA's improper meddling, see *Public Citizen v. FMCSA,* 374 F.3d 1209 (D.C. Cir. 2004) (setting aside on safety grounds a rule *extending* the hours truck drivers may drive after OIRA intervened on behalf of trucking companies to reverse the agency's proposed rule *reducing* the hours).

[11] See *Public Citizen Health Research Group v. Chao,* 314 F.3d 143 (3d Cir. 2002); 145 F.3d 120 (3d Cir. 1998) (describing pace of hexavalent chromium rule-making).

[12] I recognize that the Executive Order does not completely foreclose the possibility that OIRA will permit an agency to proceed with rule-making even if the agency cannot show that its proposed action is warranted by market failure. Executive Order 13422, § 1(b), does allow an agency to make the case to OIRA that a showing of market failure is not "applicable" to the proposed regulatory action. But there are reasons to doubt that an agency intent on skirting the market failure analysis will succeed with OIRA. For one thing, the change in the language of § 1(b) from Executive Order 12866 to Executive Order 13422 is profound; the former Order required the agency to "identify the problem that it intends to address. . .as well as the significance of that problem." The new Order deletes that language and says that "[e]ach agency shall identify in writing the specific market failure. . .or other specific problem that it intends to address. . .." That substitution plainly signals that, from now on, OIRA will expect to see an economic analysis of market failure as a precondition to regulation absent a convincing economic argument from the agency that market failure is not at the root of the "other specific problem" the agency intends to address. Moreover, the use of the word "shall" underscores that agencies have no choice but to engage in this analysis, even if the agency ultimately decides not to rest its case on market failure grounds.

basis. And for "significant" agency action—including "significant" non-binding agency guidance documents—agencies will have to demonstrate to OIRA's satisfaction that the failure of market forces warrants the action the agency seeks to undertake. Giving OIRA another tool to block agency initiatives is unwise; permitting OIRA to meddle in the substance of agency guidance is doubly unwise.

There is a related problem as well. Where agencies propose to take regulatory action, the Executive Order already requires agencies to conduct a rigorous cost/benefit analysis as part of the Regulatory Impact Analysis it must provide to OIRA. Now the amended Executive Order requires a market failure analysis as well. The Executive Branch apparently takes the view that it can continue to pile on analytical requirements on overtaxed regulatory agencies without limit and without Congress' approval. Make no mistake; each of these analytical requirements consumes scarce resources that agencies could use to carry out the instructions given to them by Congress. At some point—if indeed that point has not already been reached—the requirements imposed by Executive Order will crowd out those imposed by statute.

Third, and perhaps most problematic, while there is a modest effort in the Executive Order to define "market failure" (e.g., "externalities, market power, lack of information"), market failure is in the eye of the beholder. There is no commonly-accepted definition of the term, and, as a result, much will then depend on the definition OIRA's staff gives to the term market failure.

This concern takes on special force when one considers the views of Susan E. Dudley, President Bush's nominee to head OIRA. Ms. Dudley's writings suggest that she believes markets almost never fail, and that government intervention is therefore rarely if ever appropriate.[13] For instance, Ms. Dudley was virtually alone in opposing NHTSA's recent advanced air-bag rule. She did so on the ground that, in her view, there was no evidence of market failure, and therefore NHTSA's "attempt[] to make all vehicles equally safe for occupants" was unwarranted.[14] Ms. Dudley sees little room for government intervention in the market, even for protective health and safety regulation. Ms. Dudley's restrictive understanding of market failure raises serious questions. If Ms. Dudley saw no evidence of market failure with air bags—where the evidence of continual market failure is overwhelming—would she have insisted on clearer evidence of market failure before she let the EPA order the phase-out of lead in gasoline, the Consumer Product Safety Commission ban the use of flammable material for children's sleep-wear, or the FDA require that iron pills—the single largest cause of poisoning children in the United States—be sold in child-proof containers? We ought not wait for "market failure" to exact a toll on human health and safety before we permit our agencies to act. In the health and safety context, the only way market failure becomes apparent is when the body count gets too high. The point of regulation is to prevent market failure, not to try to remedy it once the damage is done. The Executive Order subverts that fundamental principle.

2. The Amendments Inappropriately Expand OMB's Authority and Entrench Gridlock.

Whatever the wisdom of centralized OIRA review of *binding* agency rules, the same arguments do not extend to centralized review of *non*-binding guidance. Agencies provide guidance constantly, in literally hundreds of guidance documents or interpretative missives each year. Consider just one agency. The most recent listing of the titles of guidance documents used by the Food and Drug Administration was published in January 2005. It runs nearly *ninety pages* in the *Federal Register*.[15]

Agencies often use guidance documents to help industry meet regulatory obligations in time-sensitive or emergency situations. For example, OSHA's most recent guidance document provides employers with advice about how to address an influ-

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[13] Ms. Dudley's writings are explored in depth in a report by Public Citizen and OMB Watch entitled *The Cost Is Too High: How Susan Dudley Threatens Public Health Protections* (Sept. 2006) (available at *http://www.citizen.org/publications/release.cfm?ID=7448&secID=2565&catID=126*).

[14] Susan E. Dudley, *Regulatory Studies Program Comments: Advanced Air Bags* 7 (Dec. 17, 1998) (available at *http://mercatus.org.repository/docLib/MC_RSP_PIC1998-04_NHTSA-Air-Bags_981130.pdf*).

[15] 70 *Fed. Reg.* 824–913 (Jan. 5, 2005); see also *FDA Center for Drug Evaluation and Research List of Guidance Documents* (Feb. 1, 2007) (33-page document setting forth currently in force guidance documents) (available at *http://www.fda.gov/cder/guidance/CompList02_2007.pdf*). The CRS Report cited above, *supra* n.1, notes that the Occupational Safety and Health Administration reported in 2000 that it had issued 3,374 guidance documents since March 1996, thus averaging around 1,000 guidance documents a year. CRS Report at 10, n.22.

enza pandemic,[16] one of the FDA's most recent guidance documents advises clinical laboratories on how to address public health problems that resulted from the failure of certain laboratories to properly conduct tests on human donors,[17] and one of the EPA's most recent guidance documents provides advice to manufacturers of antimicrobial agents on how to properly test and register their products with the EPA.[18]

Congress has long understood that, when it comes to the provision on guidance and advice, it is unwise to erect barriers between agencies and regulated entities and the public. Government must be accessible to those it regulates and to those who benefit from regulation. For that reason, when Congress enacted the Administrative Procedure Act, it *exempted* guidance documents and interpretative pronouncements from all of the informal and formal rule-making requirements of the Act.

Executive Order 13422 upsets Congress' judgment on that balance. Before issuing any guidance document, an agency must address in writing the question of "market failure"—an analytic requirement that will delay the issuance of sorely needed guidance. The Executive Order is also highly prescriptive about the contents of guidance documents. Rather than permit agencies to retain flexibility and tailor guidance documents to their audiences, the Executive Order instructs agencies that every guidance document must (a) be based "on the best reasonably obtainable scientific, technical, economic, and other information;" (b) be compatible and not duplicative of guidance given by other agency; (c) be "simple and easy to understand;" and (e) be tailored "to impose the least burden on society, including individuals, businesses of different sizes, and other entities. . .taking into account, among other things, the costs of cumulative regulations."[19]

Not only do "significant" guidance documents have to survive that gauntlet,[20] but also subjecting them to full-bore OIRA review invites additional, substantial delays. There is a conspicuous and undoubtedly deliberate omission in the new Executive Order. Although the amended Order retains the long-standing time constraints on OIRA to act on agency *regulatory* proposals, there is no similar time limit on OIRA's review of *guidance* documents.[21] If OIRA takes months or longer to review a guidance document OIRA deems significant, the agency has no recourse under the Executive Order. If the past is prologue, OIRA review process will certainly delay, often substantially, the issuance of needed significant guidance.[22]

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[16] OSHA, *Guidance Document for Preparing Workplaces for an Influenza Pandemic* (2007) (available at *http://www.osha.gov/Publications/influenza_pandemic.html*).

[17] FDA, Center for Biologics Evaluation and Research, *Certain Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Recovered From Donors Who Were Tested For Communicable Diseases Using Pooled Specimens or Diagnostic Tests* (Jan. 23, 2007) (available at *http://www.fda.gov/cber/gdlns/hctppool.htm*).

[18] EPA, *Regulating Antimicrobial Pesticides* (Jan. 25, 2007) (available at *http://www.epa.gov/oppad001*).

[19] Executive Order 13422, §§ 1(b)(1), 1(b)(7), 1(b)(10), 1(b)(11) & 1(b)(12).

[20] There is a definitional ambiguity embedded in the Executive Order that gives OIRA broad authority to designate virtually any guidance document "significant," triggering mandatory OIRA review. In section 3(h)(1)(A), the Order defines the term "[s]ignificant guidance document" as one that "may reasonably be anticipated to. . .[l]ead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities." Because guidance documents are by definition *non*-binding, it is difficult to see how one could "lead to an annual effect of $100 million or more," although the phrase "lead to" permits OIRA to claim that even the most indirect action by the agency could have a substantial effect on the economy. OIRA has already suggested that it will take this view. See OMB, *Final Bulletin for Agency Good Guidance Practices,* 72 *Fed. Reg.* 3432 (Jan. 25, 2007). But aside from the indirect effects point, the definition is written in the disjunctive and it is easy to see how one could argue that virtually any guidance document that addresses broad public health questions, such as OSHA's guidance on pandemic influenza or the EPA's guidance on antimicrobial agents, might be said to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety." Thus, it is difficult to tell what guidance documents might be deemed "significant." It could be that hundreds or thousands of guidance documents each year would qualify under this potentially sweeping definition—a concern heightened because OIRA, not the agency, will have the final say on what constitutes a "significant" guidance document.

[21] Compare Executive Order 13422, § 9 (requiring agency consultation with OIRA on significant guidance documents but not setting any time limit for such consultation) with id. §§ 6 & 8 (setting strict time limits for OIRA/agency consultation on regulations).

[22] The CRS Report, *supra* n.1, raises another question of omission: Executive Order 13422 does not clearly extend the transparency requirements applicable to rule-makings to OIRA review of guidance documents. CRS Report at 11–12. As I read the new Order, CRS's concerns are well-founded. There is nothing in the Order that makes explicit that the transparency and accountability provisions relating to OIRA clearance of rule-makings apply to OIRA review of guidance documents, and one may reasonably conclude that omissions of this sort are not inad-

3. Rationing of Health and Safety Protection.

Executive Order 13422 also sets the stage for the resurrection of the discredited concept of a "regulatory budget." Under the new Order, "no rule-making may be commenced" unless it appears on the agency's Regulatory Plan *and* the agency sets forth "the agency's best estimate of the combined aggregated costs and benefits of all its regulations planned for that calendar year."[23] These estimates give OIRA the ability effectively to cap the amount of compliance costs an agency may impose in a calendar year—or set a "regulatory budget"—a power OIRA has long coveted.

The goal of this amendment is quite clearly to limit industries' exposure to regulatory costs. OIRA could wield this tool regardless of whether the compliance costs will be absorbed by different industries, regardless of the benefits that flow from regulation, and regardless of the mandates Congress has set for the agencies. If Congress believes it is appropriate to experiment with regulatory budgeting, that is one thing. It is quite another for the Executive Branch to arrogate that power to itself.

4. Further Politicization of the Regulatory Process.

Executive Order 13422 breaks from past practice in another important respect: It requires each agency to designate a political appointee to head its regulatory policy office. In many agencies, the regulatory policy office has traditionally been headed by a career civil servant who is an expert in the arcane details of regulation.[24] But in all agencies, regulatory action is reviewed and approved by the agency head, or his designee, to ensure that there is political accountability for agency actions.

The amendments to the Executive Order, however, undermine the authority Congress has conferred on the agency head. This is a troubling development that Congress ought to care deeply about. The statutes Congress enacts to delegate decisional power to agencies explicitly designate the agency head—and not a subordinate—as the decision-maker. Congress is careful to designate the agency head to ensure that decisions are made by an official accountable to Congress as well as the President. To be sure, the President retains the power of appointment and removal, but Cabinet Secretaries and agency heads are presumed to have the power to decide questions independently, even at the risk of removal. Disputes between the White House and Cabinet officers and agency heads have emerged and, at times, the White House has relented.

The amended Executive Order strips Congress' designation of much of its force by giving a *different* political appointee—accountable to the President but *not* necessarily to Congress—substantial control over the agency's regulatory output. This is not hyperbole. The Order expands the duties of the policy officer, providing that, "[u]nless specifically authorized by the head of the agency, *no rule-making shall commence nor be included on the [agency's annual regulatory] Plan without the approval*" of the policy officer.[25] Under the new Order, the policy officer—who has ties with and owes his allegiance to the White House—will be the gatekeeper of the agency's regulatory output. As *The New York Times* put it, "[t]he White House will thus have a gatekeeper in each agency to analyze the costs and benefits of new rules and to make sure the agency carries out the president's priorities,"[26] which are not necessarily Congress' priorities.[27]

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vertent. Congress, of course, has at times been critical of OIRA's penchant for behind-close-door dealings in the past, and the apparent decision to shield agency-OIRA interactions over guidance documents from public view appears to be an unwarranted return to the past.

[23] Executive Order 13422, § 4(c)(1)(B).

[24] On this issue in particular, I want to endorse the views of Columbia University Law Professor Peter L. Strauss, who is testifying on Executive Order 13422 today before the House Judiciary Committee's Subcommittee on Commercial and Administrative Law. Professor Strauss suggests that Congress, not an agency head or the White House, ought to select the regulatory officer, a suggestion I endorse. The CRS Report, *supra* n.1, also suggests that this portion of the Executive Order might run afoul of the Appointments Clause on the ground that with the enhanced powers provided by the Executive Order, the policy officer must be seen as a principal officer of the United States, requiring Senate confirmation under *Buckley v. Valeo,* 424 U.S. 1, 126 (1976). Although the courts have been wary about Appointments Clause claims, the CRS Report raises serious constitutional questions that should be explored fully by Congress.

[25] Executive Order 13422, § 4(c)(1) (emphasis added).

[26] Robert Pear, Bush Directive Increases Sway on Regulation, *N.Y. Times,* A1 (Jan. 30, 2007).

[27] The CRS Report, *supra* n.1 at 7 & n.16, suggests that the problems I see in this provision of the Order may be more theoretical than real, because many of the presidential appointees in the major agencies are subject to Senate confirmation. I am skeptical of this assertion. For years, the White House has used non-career SES slots to place presidential appointees in high-level, non-confirmation positions at many agencies, such as the non-career deputy commis-

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5. The Push to Formal Rule-making.

Executive Order 13422 amends section 6 of Executive Order 12866 by adding the following: "In consultation with OIRA, each agency should also consider whether to utilize formal rule-making procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations." To administrative law scholars, the suggestion that the White House is pushing agencies to undertake formal rule-making under sections 556 and 557 of the Administrative Procedure Act is both stunning and stunningly ill-advised. To begin with, it betrays a misunderstanding of administrative law to call sections 556 and 557 "rule-making" provisions; they are not, they are "hearing" provisions. Rule-making under the APA is generally governed by section 553, which calls for notice and comment rule-making, not rule-making based on a formal hearing. Sections 556 and 557 establish procedures for formal agency adjudicatory hearings (a) where adjudications are required under section 554 of the APA or (b) in those rare instances in which Congress has specified that an agency must hold a hearing as part of its rule-making process. But agencies do not voluntarily hold hearings in rule-making proceedings. Formal hearings are notoriously cumbersome, labor-intensive, and time-consuming and agencies have long sought to avoid them by any means possible—a stratagem largely endorsed by the Courts.[28] Moreover, in the rare instances in which agencies engage in formal hearings under sections 556 and 557, the hearing is used to resolve matters of dispute between two parties, or among a small number of discrete parties—such as a proceeding to confer a license on one of two or more competing parties. Unless mandated by Congress, formal hearings have not been used to establish regulatory policy or rules of general applicability for decades, and no one has advocated otherwise, until the issuance of Executive Order 13422.[29]

The inclusion of this provision in the Executive Order heightens concern about the purpose of the Order. As I have explained, one inevitable consequence of Executive Order 13422 is that it will lead to the further ossification of an already overburdened administrative process. As an instrument of delay, formal rule-making has no peer; it is the American version of Dickens' nightmarish *Jardynce v. Jardynce.* Empowering OIRA to push agencies to employ formal rule-making to make complex determinations sends a disturbing signal, namely that delay and not resolution is the real goal.

CONCLUSION

Executive Order 13422 constitutes an unprecedented consolidation of power over our regulatory agencies in the White House. It also constitutes an unprecedented assault on the ability of Congress to set the substantive standards that guide agencies in the performance of their delegated tasks. The consequences of this shift are far-reaching and tragic. Effective regulation is essential to our nation's well-being. For that reason, administrative agencies were created to bring expertise, independence, and transparency to the regulatory process. This Executive Order undermines those values. It gives a small group of generalists at OIRA the power to second-guess and undermine the expert and impartial judgments of the scientists, physicians, epidemiologists, engineers, and toxicologists who staff our health and safety agencies. It holds health and safety regulation hostage to economic considerations of market failure and cost/benefit analysis. It puts partisan politics at the center of our regulatory process by giving the White House substantial control over the day-to-day work of our agencies. And it undermines transparency by establishing an off-the-record process for OIRA review of significant guidance documents.

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sioners at the Food and Drug Administration. The CRS Report recognizes the possibility that these appointees will qualify under the Executive Order and concedes that if these appointees qualify "then the agency heads would have a wider range of 'presidential appointee' positions from which to designate regulatory policy officers." *Id.* Because the White House alone will decide which appointees qualify as "presidential appointees" under the Executive Order, I do not believe that the narrow view of what constitutes a "presidential appointee" expressed in the CRS Report will be the one chosen by the White House, which has strong incentives to ensure that its operatives are appointed agency regulatory officers.

[28] See generally *United States v. Florida East Coast R.R. Co.,* 410 U.S. 224 (1973); *Chemical Waste Management, Inc. v. EPA,* 873 F.2d 1477 (D.C. Cir. 1989) (rejecting claim for formal hearing in part on efficiency grounds).

[29] See generally ACUS Recommendations 72–5, *Procedures for the Adoption of Rules of General Applicability,* 38 *Fed. Reg.* 19782 (1972) (arguing that proceedings under section 556 and 557 should be sharply circumscribed).

Congress has acquiesced in this accretion of power to the President. I would urge that the time has come for Congress to consider reclaiming its authority. Thank you.[30]

BIOGRAPHY FOR DAVID C. VLADECK

David C. Vladeck is the Director of the Institute for Public Representation and Associate Professor of Law at Georgetown University Law Center. He teaches courses in federal courts, civil procedure, and first amendment litigation, and co-directs the Institute for Public Representation, a clinical law program at the Law Center where he handles a broad array of civil rights, civil liberties, first amendment, open government, and regulatory litigation.

Prior to joining the Georgetown faculty in 2002, Professor Vladeck spent nearly 30 years with Public Citizen Litigation Group, serving as its Director from 1992 to 2002. He has handled a wide range of complex litigation, including first amendment, health and safety, civil rights, class actions, preemption and open government cases. He has argued a number of First Amendment and civil rights cases before the United States Supreme Court, and more than 60 cases before the federal courts of appeal and state courts of last resort.

Professor Vladeck also testifies before Congress, advises Members of Congress on legal matters, and writes on administrative law, first amendment, legal ethics, and access to justice issues. He serves as a Scholar with the Center for Progressive Reform and on the boards of various non-profit organizations. He has also served on the Council of the Administrative Law and Regulatory Practice Section of the American Bar Association, as a Public Member of the Administrative Conference of the United States, and as the Chair of the Administrative Law Section of the District of Columbia Bar. Professor Vladeck received his undergraduate degree from New York University, his law degree from Columbia University School of Law, and an LL.M. degree from Georgetown University Law Center.

Chairman MILLER. Thank you, Mr. Vladeck. Mr. Kovacs. I wasn't paying attention.

STATEMENT OF MR. WILLIAM L. KOVACS, VICE PRESIDENT, ENVIRONMENT, TECHNOLOGY, AND REGULATORY AFFAIRS, U.S. CHAMBER OF COMMERCE

Mr. KOVACS. Thank you, Mr. Chairman, and Ranking Member Sensenbrenner.

It is really a privilege to be here today, and to discuss oversight issues with federal agencies. The Chamber cares about this issue probably more than any other issue. The regulatory mill, contrary to what has been stated, has not stopped. There are about 110,000 regulations out there right now. There are 4,000 new regulations a year. The cost to the American economy is about $1.1 trillion, and to put it in perspective, there are only $857 billion in individual income taxes, and another $226 billion in corporate taxes, so it is one significant mandate. It costs small business about 45 percent more than it costs a large business to comply with it.

So, the regulatory mill, and the regulation mill, hasn't stopped. Executive Order 13422, you know, there is a lot of hyperbole and a lot of rancor about this, but this Executive Order contains nothing that hasn't been contained in an Executive Order since the Presidency of Richard Nixon, and through Nixon, with his quality of life, and Jimmy Carter, with his regulatory reform, right through Reagan and Bush and Clinton, have all issued something like this. And it is an attempt by the Administrations to get some management structure in the agencies, because what does it ask them to do? It asks them to—asks to state a purpose for the rule.

[30] I would like to acknowledge the assistance of Sandra C. George, a third-year student at Georgetown University Law Center, in the preparation of this testimony.

It asks that they have a cumulative cost benefit, which some people would say is new, but it actually came in Carter's time, and to have a regulatory appointment. That also came in Carter's time.

And during this same 30 year time period, it hasn't been as if the agencies were just off, or the executive was off trying to manage the agencies. Congress has gone through the Regulatory Flexibility Act, where you have asked the agencies every seven years to come back and talk about the regulations that should be eliminated, or Small Business Regulatory Fairness Act (SBREFA) with Congressional review, or negative—or reg negs. You can go through a whole list. This has been a bipartisan effort for 30 years, and it is an attempt to manage.

The Good Guidance Practices, yeah, we did comment on it, and most of the comments were very positive. But what does it ask the public to do? It asks the public and the agencies that if you have a significant guidance document, and some of these guidance documents are very significant, because on top of the 110,000 regulations, you have several—tens of thousands of guidance documents. What does it ask them to do? It says if it has got significant guidance, of general applicability to the entire regulated community, what should you do? You should put it on your website? That is corrupting government? You should put it on your website, and allow the public to comment? You should give them a list of documents, and put it on your website, so that the public knows what the guidance is? Everyone feels sorry—oh, the poor small business can't speak to a regulatory officer. That is foolish. They—it has got to be of general applicability, and it requires notice and comment on the website.

The second part of it is if it is an economically significant rule, which imposes costs of $100 million or more, then they have to put a notice in the *Federal Register,* and they have to accept comments from the public. I don't know that these are huge burdens, but what it does do is it opens up the transparency. Think about it. You are a small business in North Carolina, and you have got a set of regulations that are four feet long and six feet high, going up to the ceiling, and you have to deal with health issues, pensions, environmental issues, OSHA issues, and everything else, and you have got to deal with it every day, and you have ten employees.

And so, what this is doing is it is making the process more transparent, and it is putting, yes, a political figure, someone who works for the President of the United States, who is the executive officer of the United States, and is trying to manage a government that he really has a very difficult time controlling. There are all these buildings that you look at, with all these regulations coming out of these buildings, and what is he asking the political officer to do? He is saying: "Look, I have got a policy here, I want regulations that have some compliance with my Executive Orders. Would you tell me if the agency is not going to comply with my Executive Order?" I don't think that that is an unreasonable request.

And then, finally, over the years, the courts have been very clear on Executive Orders and guidance documents. I mean, on the guidance documents, Appalachia Power, the D.C. Court of Appeals made it very clear, if it has got the force and effect of law, it is a regulation, whether you call it guidance or regulation. All this Ex-

ecutive Order is trying to do is say it doesn't matter whether it is guidance or regulation, let us have the public have the right to comment.

And then, finally, even on the scope of the Executive Order, the courts have dealt with these for years, since Harry Truman and the Steel Seizure case, if the President is legislating, then it is unconstitutional. If the President is managing government, then it is within his prerogative, and I think that this is—I really thank you for having this hearing, because I think that having a discussion over the role of agencies and government is really crucial, and I think you are doing a great service to everyone.

Thank you.

[The prepared statement of Mr. Kovacs follows:]

PREPARED STATEMENT OF WILLIAM L. KOVACS

Chairman Miller, Ranking Member Sensenbrenner, and Members of the Subcommittee, thank you for inviting me here today to testify concerning the Administration's amendment to Executive Order 12866 (which is in the form of E.O. 13422) and the Office of Management and Budget's (OMB) Final Bulletin for Agency Good Guidance Practices. I am William Kovacs, Vice President of Environment, Technology, and Regulatory Affairs at the U.S. Chamber of Commerce. The U.S. Chamber is the world's largest business federation, representing more than three million businesses and organizations of every size, sector, and region. More than 96 percent of the U.S. Chamber's members qualify as small businesses.

WHY WE CARE

As a business federation, the U.S. Chamber is all too familiar with the overwhelming regulatory burdens our members face at the hands of government regulators. Each year approximately **4,000 new regulations** are issued by federal agencies, and the *Federal Register* exceeds **73,000 pages** annually.[1] Currently, there are more than **110,000 regulations** in existence,[2] not including the thousands of **guidance documents** that implement them! Since 1995, more than **44,000 new final rules** have been issued. The annual cost to implement the Nation's regulatory system exceeds the amounts collected from individual income taxes.[3]

Moreover, the cost of federal regulations to the public is estimated to be as high as **$1.13 trillion**[4]—a cost which equals almost half the amount of last year's entire federal budget![5] And the impact of federal regulations is especially severe on small businesses. For example, the annual cost of all federal regulations is, on a per employee basis, $7,647 for firms with fewer than 20 employees—nearly 45 percent higher than the $5,282 for companies with 500 or more employees.[6]

In addition, the number of paperwork burden hours—hours spent by businesses in preparing paperwork imposed by federal regulations—has skyrocketed. Last year alone, the number of paperwork burden hours imposed on the public exceeded an extraordinary **10.5 billion hours**—the highest in history—and 2.5 billion hours more than just two years ago.[7]

With the regulatory process so increasingly complex and expensive, it is easy to understand why Presidents and Congress—both Democrat and Republican—have

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[1] *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State,* by Clyde Wayne Crews, Vice President for Policy and Director of Technology Studies at the Competitive Enterprise Institute (June 28, 2006).

[2] John D. Graham, Administrator of the Office of Information and Regulatory Affairs, Testimony before the Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs, U.S. House of Representatives (Nov. 17, 2004).

[3] *Ten Thousand Commandments: An Annual Snapshot of the Federal Regulatory State,* supra, pg. 6. The amount of individual income taxes collected in 2005 was $894 billion, and the amount of corporate income taxes collected was $226 billion.

[4] *The Impact of Regulatory Costs on Small Firms,* Report RFP No. SBHQ–03–M–0522, by W. Mark Crain, Lafayette College, for The Office of Advocacy, U.S. Small Business Administration (Sept. 2005).

[5] *Budget of the United States Government, Fiscal Year 2005,* Office of Management and Budget. Accessible at: *http://www.whitehouse.gov/omb/budget/fy2005/*.

[6] *Ibid,* footnote 2, page 5.

[7] *Paperwork Reduction Act: New Approaches Can Strengthen Information Collection and Reduce Burden,* U.S. Government Accountability Office Report, GAO–06–477T, pg. 7, Washington, DC (Mar. 8, 2006).

tried, albeit unsuccessfully, to exercise some management responsibility over the system. And, similarly, it is hard to understand the current fervor over Executive Order 13422 and OMB's Final Bulletin for Agency Good Guidance Practices (GGP). The E.O. and GGP are merely the latest efforts in a long-term, *bipartisan* attempt to exercise oversight of the regulatory process. Congress certainly would not want guidance documents masquerading as regulations, adding cost and complexity to the regulatory process and without appropriate public review and comment as required by the Administrative Procedure Act (APA).

In my testimony today, I want to make three key points:

1. Regulatory reform is not new—rather it has been an ongoing *bipartisan effort* for more than 30 years;
2. E.O. 13422 and GGP are essential tools for the executive branch to exercise oversight over the regulatory process; and
3. E.O. 13422 and GGP are part of a larger government effort to ensure and maximize the quality, utility, integrity, and objectivity of information disseminated by the Federal Government.

BACKGROUND

One of the fundamental cornerstones of good government is ensuring that the public has the opportunity to participate in the policy-making process. This participation allows the public to have a voice in the making of the laws that regulate them. Public participation protects citizens from arbitrary decisions by federal agencies by enabling citizens to effectively engage in the rule-making process.

Citizens cannot participate effectively, however, without knowing all the facts. Why do we need this rule? How much will it cost to implement? How does it fit in with other regulations? Without such basic information, citizens are precluded from intelligently voicing their concerns. **Rules do not operate in a vacuum.** As such, their cost and impact *must* be considered in conjunction with other rules.

Likewise, federal agencies exclude the public by issuing documents that are not legally binding, yet effectively regulate people's behavior. By calling such documents "guidance," they circumvent the public participation requirements guaranteed by the APA. By law, agency advisory opinions and guidance documents have no legally binding effect. They are merely an agency's interpretation of how the public can comply with a particular rule or regulation. Unfortunately, however, the use of guidance documents to regulate the public has become a common practice. That is, even though guidance documents do not have legally binding effect, they have practical binding effect when the agencies use them to establish criteria that affect the rights and obligations of private persons.

It is far easier to issue a guidance document than to undergo the rigors of rulemaking. Consider that rule-makings require internal agency review, public participation (including notice and comment under the APA), compliance with the analytical requirements of Executive Order 12866, the *Regulatory Flexibility Act,* and the *Unfunded Mandates Reform Act,* OMB review, Congressional review, and potentially judicial review. Because of these stringent requirements, agencies have a strong incentive to issue rules as less procedurally onerous guidance documents that—intentionally or not—cut the public and the regulated community out of the process.

The problem with regulations and guidance documents is symptomatic of a larger problem concerning the entire regulatory system. But, over the years, efforts have been made to address it.

I. REGULATORY REFORM HAS BEEN A BIPARTISAN EFFORT

For years, the Executive and Legislative branches of government—*regardless of party or politics*—have tried hard to exercise oversight over a cumbersome, complex, and often times inequitable regulatory system.[8] Through a vast array of executive orders and statutes, efforts to inject sanity into the regulatory process have made slow, but noticeable, progress.[9] As guidance document abuse became more and more

[8] For example, Executive Order 12044, Improving Government Regulations, signed by President Carter in 1978, established requirements for centralized review of regulations and the preparation of regulatory analyses, and mandated that agencies "periodically" review existing regulations. Executive Order 12866, Regulatory Planning and Review, was signed by President Clinton in 1993 and required agencies to review existing regulations to identify which could be modified or eliminated. Section 610 of the *Regulatory Flexibility Act* requires federal agencies to review regulations every 10 years to determine whether they are meeting their objectives and if they should be rescinded.

[9] See Appendix A.

prevalent,[10] however, Congress again intervened to try to correct the inequity. In 2000, the House Committee on Government Reform adopted a report titled "Non-Binding Legal Effect of Agency Guidance Documents," which highlighted agency abuse of guidance documents and severely criticized the use of such so-called "back-door regulation."[11] Still, agencies continued to issue guidance to effectively regulate the public. The judicial branch eventually weighed in, with courts alerting congress to the problem, and encouraging legislation to correct it:

> The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the *Federal Register* or the *Code of Federal Regulations.*[12]

While presidential and Congressional efforts at regulatory reform have improved the system, much work remains to be done.

II. THE E.O. AND GGP ARE ESSENTIAL TO EXERCISING OVERSIGHT OVER THE REGULATORY PROCESS

a. E.O. 13422

When President Bush signed Executive Order 13422, he was expanding the scope of E.O. 12866, issued under President Clinton, to include not just rules, but also, for the first time, guidance documents. This would serve to correct the abuse of guidance documents by federal agencies seeking to avoid public participation in the policy-making process. Far from being radical, E.O. 13422 merely instructs federal agencies to:

1. State the reason for the regulation;
2. State the cost of the regulation, and an estimate of the combined costs and benefits of all of its regulations planned for that calendar year (to assist with the identification of agency priorities); and
3. Have a Regulatory Policy Officer ensure that these requirements have been followed by the agency.

Perhaps the most talked about requirement in E.O. 13422 has been the appointment of a Regulatory Policy Officer (RPO) by the President. Critics have declared that this provision is an illegal expansion of executive authority because it allows the President to control the regulatory agenda. Yet what is it the RPO is tasked to do? First, the RPO ensures that any guidance document is not actually a rule—one that will regulate public behavior. Second, the RPO ensures that the agency has explained the need for a rule, and has looked at the costs and benefits of the proposed rule, and the aggregate costs and benefits of all the rules being issued by that agency for the year. If it hasn't, then the RPO can notify OMB. Is it really so insidious to require accountability in our rule-making process?

Nevertheless, critics continue to decry E.O. 13422 as an unwarranted (and possibly unconstitutional) expansion of executive power. Yet, without delving into a constitutional law treatise on the subject—which is beyond the scope of this testi-

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[10] Perhaps the most notorious example of an agency guidance document regulating behavior is EPA's "Interim Guidance for Investigating Title IV Administrative Complaints Challenging Permits" (the so-called "Environmental Justice" guidance), which a GAO investigation subsequently concluded was a rule disguised as guidance.

[11] H. Rep. 106–1009 (106th Cong., 2d Sess. 2000).

[12] *Appalachian Power Co. v. EPA,* 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment). See also, *Chamber of Commerce v. Dept. of Labor,* 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment); *General Electric Co. v. EPA,* 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment). Even the American Bar Association, recognizing the problem with guidance documents, stated in its *Annual Report Including Proceedings of the Fifty-Eighth Annual Meeting,* August 10–11, 1993, Vol. 118, No. 2, at 57: "Before an agency adopts a non-legislative rule that is likely to have a significant impact on the public, the agency must provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when non-legislative rules are adopted without prior public participation, immediately following adoption, the agency must afford the public an opportunity for post-adoption comment and give notice of this opportunity."

mony—it is certainly well settled that the President has the power to make political appointments of officers within his own executive agencies.[13] Hysterical claims of unconstitutional "power grabs" only serve to distract us from the important and sizable problems with the regulatory process that E.O. 13422 is intended to address.

b. GGP

The final version of OMB's GGP bulletin, released simultaneously with the President's E.O. 13422, establishes policies and procedures for the development, issuance and use of significant guidance documents in order to increase the quality and transparency of internal agency practices. The purpose of GGP is to ensure that guidance documents of Executive Branch departments and agencies are developed with appropriate review and public participation, accessible and transparent to the public, and not improperly treated as legally binding. The GGP also provides a distinction between what does and does not constitute a guidance document to provide greater clarity to the public.

Such criteria are not new. In fact, there is a strong foundation for establishing standards for the initiation, development, and issuance of guidance documents to improve their quality and transparency. The former Administrative Conference of the United States (ACUS), for example, developed recommendations for the development and use of agency guidance documents.[14] In 1997, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices.[15] Congress then codified aspects of the FDA document into the *Food and Drug Administration Modernization Act of 1997*.[16] Much of GGP is modeled on the FDA's early efforts.

III. E.O. 13422 AND GGP ARE PART OF A LARGER GOVERNMENT EFFORT TO INCREASE TRANSPARENCY AND MAXIMIZE THE QUALITY, UTILITY, INTEGRITY, AND OBJECTIVITY OF INFORMATION DISSEMINATED BY THE FEDERAL GOVERNMENT

E.O. 13422 and the GGP are part of a long effort by Congress and several Administrations to improve the transparency and quality of government data and provide effective parameters to guide the regulatory activities of federal agencies.[17] These efforts finally coalesced in the passage of the *Information Quality Act* (IQA) in 2001, which serves as the basis for the issuance of the GGP. Were it not for a unified commitment to quality data by this and former Administrations and Congresses—as exemplified in the passage of the IQA—the GGP would not exist today.

In order to understand the connection between GGP and IQA, it is helpful to understand what the IQA really is.

More than any law before it, the IQA served to promote integrity in the agency decision making process, and to enhance the accuracy of the data underlying government regulatory decisions. It does this by creating a mechanism by which the public can challenge poor data. In this way, the IQA is a tool for everyone—from industrialists to environmentalists—providing equal opportunity to correct faulty government data.

Data quality is a matter of great importance to all of us. For me to have confidence that my decisions are sound, I must have good information. This is just plain common sense. Similarly, Members of Congress must be able to rely on their staff to provide good information. Why shouldn't we be able to expect United States government agencies to do the same, that is, rely on good information when developing regulations and guidelines?

The IQA seeks to assure that this expectation can in fact be realized. It requires federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of disseminated information and establishes a system whereby interested parties can seek correction of erroneous, disseminated information. Ideally, the Act improves information quality, and in so doing, provides a firmer basis for regulatory authorities to make sound policy decisions. This is why the Chamber has been one of the strongest proponents of the IQA.

At the time of its passage, just like now with the issuance of E.O. 13422 and the GGP, many critics insisted that the IQA would "shut down" the regulatory process, result in thousands of regulatory challenges, and ultimately rollback environmental, health and safety protections in this country. Of course, nothing of the sort occurred.

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[13] Article II, U.S. Constitution.

[14] ACUS, Rec. 92–2, 1 C.F.R. 305.92–2 (1992).

[15] Notice, "The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents," 62 FR 8961 (Feb. 27, 1997).

[16] Public Law No. 105–115.

[17] See Appendix A.

In fact, in FY 2005 only 27 IQA petitions were filed with federal agencies. And only 12 IQA appeals were handled by federal agencies that year—two new appeals, and 10 from FY 2003 and FY 2004.[18]

Nevertheless, even faced with these facts regarding the IQA, there are still people that claim the law is an underhanded attempt by industry to stymie the regulatory system. It is difficult to understand why people wouldn't want regulations based on the most accurate and objective available data. It is likely they are the same people that are currently decrying E.O. 13422 and GGP, and, consequently, time will again prove them wrong. But more importantly, it is essential that federal agencies clearly explain to the American public why they are issuing rules, and the cost of these rules. For after all, it is the American public that must live under these rules, and as a society of laws, not of men, it is not unreasonable to ask that our government clearly explain to us what they are asking us to obey, particularly when disobedience results in severe civil and criminal penalties.

CONCLUSION

The long-standing debate over regulatory reform will not end today. The U.S. Chamber strongly believes that the regulatory reform process is critical to ensuring that regulations and guidance documents are sound, balanced, cost-effective, and open to the public. Congress must not abandon its oversight role in this area, and the U.S. Chamber applauds this committee for this hearing today.

The U.S. Chamber is grateful for the opportunity to present its views about this important topic.

BIOGRAPHY FOR WILLIAM L. KOVACS

Bill Kovacs provides the overall direction, strategy, and management of the Environment, Technology & Regulatory Affairs division of the U.S. Chamber of Commerce, the world's largest business federation representing more than three million businesses of every size, sector, and region.

Since assuming the position of Vice President in March 1998, Mr. Kovacs has transformed a small division that has focused on a handful of issues and committee meetings into one of the most significant in the institution. Presently, the Environment, Technology & Regulatory Affairs division initiates and leads complex, multidimensional, national issue campaigns for such significant issues as comprehensive energy legislation, the permanent storage of spent nuclear fuel, telecommunications reform, and the systematic application of sound science to the federal regulatory process.

Throughout his tenure at the U.S. Chamber, Kovacs has focused on finding new leadership opportunities for the institution. He pioneered the use of cybercasting for Chamber events in 1998, recruited and assembled the first science team to work in tandem with policy staff to ensure that federal regulations are based on sound science, formed and chaired the Chamber's Technology Coordinating Group, and helped to develop numerous national coalitions in the areas of environment, energy, regulatory affairs, and technology.

Prior to joining the U.S. Chamber, Kovacs was Director of worldwide legal affairs for Sunshine Makers, Inc., manufacturer of the Simple Green line of non-toxic cleaning products. Additionally, Mr. Kovacs held the position of partner in several Washington, D.C. law firms where his practice focused on environmental law.

As for government service, Kovacs served as Vice Chairman and Chairman of the Commonwealth of Virginia's Hazardous Waste Facilities Siting Board, as Chief Counsel and Staff Director for the U.S. House of Representatives Subcommittee on Transportation and Commerce, and as Legislative Director and Counsel for a member of Congress.

During his tenure as Chief Counsel, Mr. Kovacs was the primary counsel on two landmark laws that were enacted in a single session of Congress: the *Resource Conservation and Recovery Act,* the primary federal law that regulates solid and hazardous waste; and the *Rail Revitalization and Regulatory Reform Act* that re-organized the bankrupt Penn Central Railroad into Conrail, the largest corporate reorganization in the United States at the time.

Mr. Kovacs is a frequent commentator on national environmental, energy, and regulatory issues that impact the business community. He is regularly quoted in the Nation's leading newspapers and appears on talk radio and television as a spokes-

[18] 2006 Report to Congress on the Cost and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, OMB's Office of Information and Regulatory Affairs. January 2007.

person for American business. He is listed in *Who's Who in the World, Who's Who in America, Who's Who in American Law,* and *Who's Who in Emerging Leaders.*

Mr. Kovacs holds his law degree from the Ohio State University College of Law and his Bachelor of Science degree from the University of Scranton, magna cum laude.

CHAMBER OF COMMERCE
OF THE
UNITED STATES OF AMERICA

WILLIAM L. KOVACS
VICE PRESIDENT
ENVIRONMENT, TECHNOLOGY &
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February 8, 2007

The Honorable Brad Miller
Chairman
Subcommittee on Investigation and Oversight
United States House of Representatives
Washington, DC 20515

Dear Chairman Miller:

My name is William L. Kovacs, Vice President of Environment, Technology & Regulatory Affairs with the U.S. Chamber of Commerce. I will be testifying before your subcommittee on February 8, 2007, at a joint hearing titled "Amending Executive Order 12866: Good Governance or Regulatory Usurpation?" In accordance with the Rules of the Committee, I am writing to let you know that I have no financial interests that are relevant to the subject matter of my testimony.

Thank you.

Sincerely,

William L. Kovacs

Chairman MILLER. Thank you, Mr. Kovacs. The Chair, on behalf of the Subcommittee, welcomes that endorsement.

Dr. Melberth.

STATEMENT OF MR. RICK MELBERTH, DIRECTOR OF REGULATORY POLICY, OMB WATCH

Mr. MELBERTH. Thank you, Mr. Chairman.

You have heard testimony about the Executive Order amendment, so I would like to focus my comments on the tools of the regulatory process that Mr. Vladeck referred to.

A great deal of attention has been given to things like cost-benefit analysis, risk assessment, peer review and federal advisory committees have been the focus of more recent attention. The Administration has consistently used regulatory tools like risk assessment, peer reviews, and federal advisory committees to manipulate science for its own ends, attempted to impose a one size fits all framework on the agencies' use of these tools, and has shifted the criteria for defining when regulations are necessary away from a health and safety problem and toward a market-based criteria.

Cost-benefit analysis is often touted by the Administration and conservative think tanks as a neutral tool in policy-making, but recent studies by legal scholars show that the CBA is inherently political. There are several shortcomings in the way CBA is used, and these deficiencies have been exacerbated by actions during the Bush Administration.

A second regulatory tool that OIRA tried to manipulate was the use of risk assessments. In January 2006, John Graham issued OMB's proposed Risk Assessment Bulletin, which contained a set of one size fits all guidelines to govern all risk assessments, and included technical standards for all federal agencies to use when conducting risk assessments, as well as other scientific documents.

The National Research Council's review of the Bulletin called for its withdrawal. The rebuke by the NRC is one of the strongest commentaries issued on a trend over the last six years to centralize power over the regulatory process. The strongly worded NRC evaluation should provide a Congress interested in executive oversight with a strong example of the dangers of this regulatory trend.

OMB again attempts a one size fits all approach that doesn't consider different agency functions and expertise required to implement legislation in its use of peer review. OMB is a political office working directly for the Administration, not an unbiased scientific office, yet the agency places itself in the role of supervisor for implementing scientific peer review.

The science community has often argued that by appointing people from the regulated industries as members of federal advisory committees, as the Bush Administration has consistently done, the advice the committees offer to an agency might create real dangers to public health and safety. This is one example of the growing influence of regulated industries in the rule-making process.

Like the tools discussed above, federal advisory committees specifically, and the processes in which they are used, are being manipulated to achieve results desired by political considerations, not science, health, safety, or environmental protection.

OMB Watch has several concerns about the trends in the regulatory process that have occurred over the last few decades, such as the reduced governmental role, devolving responsibility to the states, and privatization. The Bush Administration has further reduced the role of the Federal Government's general welfare protections by putting special interest concerns above the general public's concerns.

There has been a sustained attack upon scientific integrity, on the quality of scientific information, on the scientific expertise of agency professionals, and on the integrity of the scientific process. The tools have been manipulated, and the Executive Order amendments just issued, coupled with the Good Guidance Practices Bulletin, have further established control over the regulatory process in the executive branch, and OIRA especially, at the expense of both Congressional power and agency discretion.

The real loser, however, is the public. In the end, less regulation means less protection. Every year, more than 40,000 people die on our nation's highways; food-borne illnesses kill an estimated 5,000, and sicken 76 million; nearly 6,000 workers die as a result of injury on the job, with an additional 50,000 to 60,000 killed by occupational disease; and asthma, linked to air pollution, is rising dramatically, afflicting 17 million, including 6 million children.

I want to leave you with just one example of the danger of this regulatory process. The Transportation Recall Enhancement Accountability and Documentation Act, TREAD, passed by Congress in November 2000, required that "The Secretary of Transportation shall complete a rule-making for a regulation to require a warning system in new motor vehicles to indicate to the operator when a tire is significantly under-inflated." Yet, the tire pressure alert system regulations that were significantly—that were required by law to be in place by the end of 2000 have not been adequately developed, although the National Highway Transportation Safety Administration determined in its rule-making that a direct tire pressure monitoring system should be installed in new vehicles.

But OMB sent a letter to NHTSA, after meeting with the auto industry, directing—deciding that the direct system was inappropriate, claiming its cost-benefit calculations provided a basis for delaying the requirement of the direct systems. The final rule, issued May 2002, would have allowed lawmakers, I am sorry, would have allowed automakers to install ineffective tire pressure monitoring systems, and would have left many drivers unaware of the dangerously under-inflated tires. NHTSA was sued because its final rule would have allowed manufacturers to choose to install either an effective direct system or an inferior indirect system.

In August 2003, the U.S. Court of Appeals for the Second Circuit ordered NHTSA to rewrite the rule, because NHTSA acted in an arbitrary and capricious manner by writing a standard that would allow installation of a clearly faulty indirect system.

Thank you, Mr. Chairman. I see my time is up.

[The prepared statement of Mr. Melberth follows:]

PREPARED STATEMENT OF RICK MELBERTH

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify before you today. I am Rick Melberth, Director of Regulatory Policy for OMB Watch. OMB Watch is a nonprofit, nonpartisan research and advocacy center promoting an open, accountable government responsive to the public's needs. Founded in1983 to remove the veil of secrecy from the White House Office of Management and Budget, OMB Watch has since then expanded its focus beyond monitoring OMB itself. We currently address four issue areas: right to know and access to government information; advocacy rights of nonprofits; effective budget and tax policies; and the use of regulatory policy to protect the public.

My testimony focuses on 1) the amendments to E.O. 12866 and the impacts of the amendments, 2) the manipulation of the analytical tools used in the regulatory process as part of a broader assault by this administration, and 3) a brief description of actions Congress might take to minimize the impact of the changes just enacted.

I. Amendments to E.O. 12866: Executive Order 13422

On January 18, President Bush issued amendments to Executive Order (E.O.) 12866, which further centralize regulatory power in the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) and shift it away from the federal agencies given this power by legislative enactments. It is another brick in the foundation this administration has been building for a unitary theory of the presidency, one in which the executive is superior to the other branches in our constitutional system and one in which the White House exhibits significant control.

We are particularly concerned with three aspects of the amendments: the identification of "market failure" as the first principle in promulgating regulations, the designation of a presidential appointee as the Regulatory Policy Officer in each agency covered by the E.O., and the requirement that significant guidance documents undergo nearly the same OIRA review process required of significant regulations. Attached to this testimony is a copy of our analysis of the amendments. I want to focus on these three aspects here.

A. The Market Failure Criterion

Through amending the regulatory process, the President is institutionalizing an anti-regulatory approach by using a market failure criterion in place of actually identifying threats to public health and safety. It diminishes standards Congress may require agencies to use, such as the best control technology, by elevating a new market failure standard that Congress has never required.

The market failure criterion is yet another layer added to the agency analysis. The agency must comply with statutory criteria (such as best available technology) as well as perform an analysis demonstrating market failures. If the agency meets OMB's standards for assessing "whether any new regulation is warranted," then the agency must also comply with other standards in the E.O., including cost-benefit analysis. We believe this new standard decidedly favors the regulated community and places another hurdle for agencies to promulgate health, safety, and environmental regulations, and creates more delay.

In addition, the language of the amendments makes clear that this economic test is front and center in the review process. Compare the language:

E.O 12866	E.O. 13422
Each agency shall identify the problem that it intends to address	Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address
(including where applicable, the failures of private markets or public institutions that warrant agency action)	(including, where applicable, the failures of public institutions) that warrant new agency action,
as well as assess the significance of that problem.	as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.

Not only is the market failure test a primary consideration, but the agency's description of the problem will be used to "enable assessment of whether new regula-

tion is warranted." This clearly forces the agency to think again about whether the best course is to do nothing and provides OIRA with another justification, or assessment, for halting or delaying regulations. The regulatory process set out in the executive order applies after Congress has passed legislation having determined that a problem existed and needed to be addressed. Under the amendments, agencies are directed to ask that same question again: is the problem worth addressing? Moreover, OIRA's assessment of whether any new regulation is warranted raises the question of whether OMB intends to supersede legislative intent when the market failure test does not met OIRA's satisfaction. Although Congress may have already legislated, without the implementing regulation, the legislation may not be able to be executed. Thus the executive branch has assumed a legislative function.

Adding the market failure criterion challenges the role of Congress. Theoretically, employees could contract with employers for a certain level of risk in their jobs. Nevertheless, Congress has passed workplace safety regulations (as well as consumer protections, environmental protections, and economic protections to help markets function better for businesses) where markets might have resolved problems if given time. As Georgetown University law professor Lisa Heinzerling wrote: "Judging regulations implementing these laws based on whether the regulations respond to 'market failure' misunderstands the premises of many of the laws Congress enacts." In short, there are multiple contexts in which Congress might justify taking legislative action, market failure being only one.

The supporters of using the market failure criterion believe the free market will supply the protections the American people want without government intervention. Susan Dudley, one of these free market advocates and the nominee to head OIRA, would have preferred to leave safety to the unsteady hand of the market, hypothesizing that "[i]f air bags protect lives, and consumers demand them, it is reasonable to assume that automobile manufacturers would have installed air bags in the absence of federal requirements to do so."[1] According to Dudley, federal action requiring air bags in cars was unnecessary because the market would have provided air bags to the public absent regulation.

OMB Watch believes that the market failure criterion is a furtherance of the economic criteria which OIRA has increasingly required as justification for taking regulatory action. OIRA has substituted economics for all other values the American public has consistently said to be important to them.

B. The Regulatory Policy Officer (RPO)

The amendments require each agency to have a Regulatory Policy Office run by a political appointee and that "no rule-making shall commence nor be included" for consideration in the agency's regulatory plan without the political appointee's approval. This will further politicize the rule-making process and provide more White House control over the agency rule-making process.

Section 4(c) The Regulatory Plan, is amended to place this regulatory planning authority directly in the RPO's hands. The language is changed from

> The Plan shall be approved personally by the agency head and shall contain at a minimum:

to

> Unless specifically authorized by the head of the agency, no rule-making shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office, and shall contain at a minimum:. . .
>
> > (B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits **of each rule as well as the agency's best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities;** [emphasis added].

The amendments add the highlighted language which requires not only significantly more analysis by the agencies because of the "best estimates" requirement, but also provides a basis to allow the RPO to establish priorities.

A similar approach was attempted by President Reagan through his E.O. 12498, the Regulatory Planning Process, which was issued January 4, 1985. Under E.O. 12498, agencies were to get approval from OMB prior to starting a rule-making—

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[1] Susan E. Dudley, *Regulatory Studies Program Comments: Advanced Air Bags 7* (Dec. 17, 1998), available at *http://mercatus.org/repository/docLib/MC_RSP_PIC1998-04_NHTSAAirBags_981130.pdf.*

a pre-rule-making review. Many in the business community thought this would be a wonderful approach for choking off agency ideas before they ever really got going. That approach, however, proved too cumbersome and difficult to administer. In short order it failed.

The new Bush E.O. amendments have the same objective, but put the choke-hold in the agencies, instead of at OMB. To ensure that the process works, the amendments grant authority to these new political appointees to be the eyes and ears for OMB. And it again mounts a challenge to congressional authority. In writing legislation, Congress often directs agencies to initiate a rule-making. The presence in the agencies of these appointees by whom rule-making must now be initiated creates a process that is as if Congress had not directed the agencies to act, or as if that direction is irrelevant if the White House appointees disagree with it.

A civil servant reacting to the new amendments provided an agency perspective (*http://fromthearchives.blogspot.com/2007/01/long-and-esoteric-twice-in-one-day-just.html*).

> From the perspective of a low level bureaucrat looking up the line, there are two big problems with this, independent of ideology.
>
> The first is simple. I just don't want to add a single step that adds time to management review. Honestly, you'd be shocked how long it takes for us to get anything through management review. Anything we release to the public, including our non-controversial, small scale documents, must go through six (6) levels of review. We schedule three to four weeks for management review. Yeah. Three days on each desk, if we give them advance notice that our stuff will be coming. If we were doing controversial stuff, it would be longer. If we had to route through one additional back-logged office? If they were far away, and my boss man couldn't chat with them to prep them for the document, and we were just another insignificant office on the west coast? I can't even guess.
>
> But the more important reason is that a distant political appointee, even assuming that she is not a partisan hack and that she is interested in the topic and not using the office as a stepping stone, would know exactly the wrong amount. Anyone at a distance from the process can only know enough to be dangerous. When we go to write anything that tells people what they have to do, there is an intricate multi-year negotiation between everyone involved. There are drafts, and comments, and drafts, and workshops, and drafts, and internal meetings, and drafts, and formal written comment, and more drafts. Usually, in the end, you will come down to very awkwardly written compromises that no one will sue you for.
>
> Every word in there was hard fought. People snorted and sat back at the table with their arms crossed. We changed it until no one threatened to call their congress person any more. We explained to them why we have to implement the law that way, and caved when we couldn't get more, or when we were wrong. We brought in someone's good idea. I know how people laugh at ridiculous regulations, but I swear they didn't get to be ridiculous because no one was thinking. They're ridiculous because the topics are complicated, and we have to accommodate widely divergent views, and because there were so many iterations.
>
> Anyway, a political appointee who wasn't there for the painful years of writing regulations can only disrupt a very precarious balance. . .. Unless she was there, she can only make things worse. I don't want her in the loop.

Even worse, if the political appointee is a "partisan hack," then the integrity of the science may be compromised. The regulatory process is a complex one that involves agency experts of all types. Imagine if a political appointee were to shape the regulatory options from the start: invariably the outcomes would be skewed.

There are two concerns with the Regulatory Policy Officer approach. First, OIRA may be creating political outposts in each agency thereby magnifying its impact. The amendments to the E.O. allow OIRA to play an active role during the pre-rule-making stage when agencies are formulating annual plans for regulatory activities. OIRA will be able to quash any contemplated regulatory or guidance issues before agencies propose them for the Regulatory Plan. Under the amended E.O., OIRA can now engage the agency, along with other government personnel (as provided for in one amendment), in reaching a "common understanding" on regulatory efforts.

Second, the content to be collected raises questions about priorities. Collecting cumulative costs and benefits leads to little more than comparing apples and oranges. And what value does this information provide to policy-makers? We believe this is leading to the creation of regulatory budgets which would be used to determine the regulatory agenda without congressional approval. Using these budgets, regulation

proceeds on a cost effectiveness basis only, with agencies' budgets ranked by total costs and benefits. It completely divorces policy-making from the need for health, safety and environmental protections.

C. Guidance Document Review

The amendments issued to E.O. 12866 require review by OIRA of agencies' guidance documents for the first time. These documents are issued to clarify how regulated parties are expected to implement legally binding regulations. By subsuming guidance documents into a review process almost identical to the review process OIRA uses to review and approve regulations, the extent of OIRA's reach into agencies' responsibilities will be at an all-time high.

By requiring agency guidance documents to come under OIRA review, and to treat "significant" guidance in the same way as "significant" regulations, the E.O. amendments will lead to further delay in providing information to the public about compliance with regulations, as well as with general guidance on agency policies.

If it is true that more and more agencies are using guidance as a means of avoiding the regulatory process, then that should be a signal to Congress and the public that the rule-making process is seriously flawed. If agencies are looking for faster ways of doing their job and have turned to guidance, the solution is certainly not to require guidance to go through the same regulatory process that agencies were trying to avoid in the first place.

The *Final Bulletin for Agency Good Guidance Practices,* issued the same day as the E.O., defines guidance documents to include "interpretive memoranda, policy statements, guidances (sic), manuals, circulars, memoranda, bulletins, advisories, and the like." Federal agencies issue thousands and thousands of guidance documents each year relating to hundreds of different types of activities. All of these documents deemed significant will now come under review by OIRA's staff of 55 people.

The fourth part of the "significant guidance document" definition, whether the issue raises "novel legal or policy issues arising out of legal mandates, the President's priorities, or principles set forth in this Executive order," is nearly broad enough to permit OIRA to sweep into its review any guidance it wishes to review.

Section I.5 of the *Bulletin* adds a further category of guidance document, the "economically significant guidance document" which is:

> "a significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include guidance documents on federal expenditures and receipts."

The definitions of both significant and economically significant guidance documents include documents that "may reasonably be anticipated to lead to" certain conditions. The *Bulletin* "makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules." In other words, it will be even easier to reasonably anticipate that a guidance document will have a significant effect on the economy than will a regulation. The reasonable people doing the anticipating no doubt work for OIRA.

Furthermore, according to the Bulletin, the "relevant economic impacts include those that *may be* [emphasis added] imposed by federal agencies, State, or local governments, or foreign governments that affect the U.S. economy, as well as impacts that could arise from private sector conduct." This creates a largely speculative analysis to be conducted by the agencies even assuming reasonably anticipated effects by a third parties. The *Bulletin* does not, however, require a formal regulatory impact analysis, so it is unclear just how this determination is to be conducted.

The example cited in the *Bulletin* of an economically significant guidance document is an agency pronouncement that a particular product or substance is unsafe. In this instance, "Unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures." The determination that a substance or product is unsafe involves some scientific assessment. This provides an example of OIRA reviewing a scientific conclusion and having the opportunity to substitute an economic analysis for a scientific one. This substitution, or even second-guessing the scientific judgment, could lead to substantial delays in protecting the public.

In the end, the review of guidance documents by OIRA will simply result in more delay and more White House control over the substantive work of the agencies. It will inevitably lead to a usurpation of agencies' powers.

II. Manipulation of Regulatory Tools

A great deal of attention has been given to the tools of the regulatory process, especially cost-benefit analysis (CBA). More recently, risk assessment (RA), peer review, and federal advisory committees (FAC) have also been the focus of attention from a regulatory standpoint. I want to address each of these briefly and to convey to the members that these tools have been manipulated by OIRA and Administration appointees to achieve results-oriented processes and biased decisions that have delayed, dismantled or diminished public protections.

A. Cost-benefit Analysis

CBA is a policy-making tool by which the costs of imposing a regulation are weighed against the potential benefits of reducing the harm. For example, in the case of pollution regulation, cost is generally construed as the cost of implementing technology to comply with regulation. These costs are more easily quantifiable than other factors, although some evidence exists that costs are often inflated.

The benefits of a regulation require two separate analyses: an assessment of the risk posed by the harm in question as well as a monetization of the potential benefits. Both factors prove to be difficult to calculate; many benefits resist monetization, and risk assessments can be hindered either through incomplete data sets or a large degree of indeterminable factors. In order to estimate the health effects of a regulation, for example, agencies generally must rely on laboratory data on other species or on human experience with much higher levels of exposure. To extrapolate from this data the potential benefits of a regulation requires a large degree of guesswork, and agencies often come up with wide ranging numbers on the potential health benefits.

CBA is often touted by the Administration and conservative think tanks as a neutral tool in policy-making, but recent studies by legal scholars show that CBA is inherently political and may even advise against what we consider our most immutable public protections.[2]

I would argue that there are several shortcomings in the way that CBA is used, and these deficiencies have been exacerbated by actions during the Bush Administration:

- The overriding criterion of CBA is efficiency, but efficiency doesn't mean fairness. The net benefit calculation that results from using CBA is without regard for who wins and who loses, and without regard for any public participation. This focus on efficiency is critical to business but doesn't work for government because there is no single, public sector measurement comparable to profit maximization in the private sector.
- CBA tends to overestimate costs for a variety of reasons. Agencies generally rely on the regulated industries to provide them with costs of compliance over a certain number of years. Studies show compliance costs drop after regulation due to the decline in the costs of technology (like pollution controls), management efficiencies, and business innovations. These cost savings, however, are not calculated into the analysis generally; and CBA takes a snapshot of one point in time resulting in a static analysis.
- The major objection I have to relying on CBA as the determinative factor in rule-making is that it does such poor job of calculating benefits. How do you monetize benefits like clean drinking water, good health, being alive? There are certain values we hold dear that cannot be adequately monetized. A decision making process that doesn't provide for the expression of these non-quantifiable benefits is critically flawed.[3]

CBA has been part of the rule-making process since the Reagan Administration. Prof. Sally Katzen spoke at a September 2006 panel on presidential rule-making and stated that, although E.O. 12866 kept the CBA requirements of the earlier Reagan era executive orders, during her tenure as OIRA Administrator,

> we explicitly recognized that non-quantifiable costs and benefits are essential to consider. That not everything can be counted and it is very important to take

[2] See, for example, Lisa Heinzerling, Frank Ackerman and Rachel Massey's *"Applying Cost Benefit Analysis to Past Decisions: Was Environmental Protection Ever a Good Idea?,"* David Driesen's *"Is Cost-Benefit Analysis Neutral?,"* and Richard Parker's *"Is Government Regulation Irrational? A Reply to Morall and Hahn."*

[3] See for example, Heinzerling and Ackerman's *Priceless: On Knowing the Price of Everything and the Value of Nothing.* NY: The New Press, 2004. Chapter 2.

into account those things which can't be counted. We also made it clear that this economic analysis was not dispositive, but simply informative.[4]

In the hands of the Bush Administration, and particularly in those of John Graham, OIRA Administrator from 2001–2006, CBA has risen to a position of primacy in the rule-making process. In September 2003, OIRA issued final guidance that instructed federal agencies on specific analytical methods for regulatory decisions. This guidance committed agencies to increased emphasis on cost-effectiveness analysis as well as benefit-cost analysis and raised the bar on new health, safety and environmental protections. Specifically, the guidance

- pushes for health and safety benefits to be expressed in terms of dollars and cents, so agencies can calculate and demonstrate "net benefits" (benefits minus costs);
- uses cost-effectiveness analysis which does not monetize benefits. Rather, it looks at the ratio of costs to units of benefits (i.e., number of lives saved). The Clinton guidance allowed agencies to use cost-effectiveness analysis in place of a "net benefits" analysis if they have difficulty monetizing. The new guidance requires both types of analyses for all major health and safety rules.
- requires discounting of lives saved in the future. "Discounting"—already common practice in monetizing benefits—rests on the premise that a life saved today is worth more than a life saved tomorrow. The further in the future a life is saved as a result of regulatory action today, the more it will be discounted from its "present value," and the less likely the action will pass a cost-benefit test.
- promotes use of "life years" in evaluating fatality benefits. Agencies commonly base benefit estimates on the "value of a statistical life" (VSL), drawn from the number of lives expected to be saved by regulatory action. On top of VSL estimates, OIRA's guidance asks agencies to consider using "value of statistical life years" (VSLY), which looks at the number of life years saved as opposed to the number of lives. This would skew against protections for the elderly, who have fewer life years remaining.

These CBA and cost-effectiveness requirements are offensive for the devaluation of lives, health and safety. Elderly and minority communities frequently suffer the consequences of a lifetime's exposure to industrial contaminants, including heart or lung failure from smog and soot, and cancer from toxic chemicals. Tens of thousands die prematurely every year as a result. They are offensive also for their elevation of economic and statistical manipulation that results in extremely high barriers to implementing public protections under the guise of regulatory relief for special interests.

B. Risk Assessment (RA)

A second regulatory tool that OIRA tried to manipulate was the use of risk assessments. In January 2006, Graham issued OMB's *Proposed Risk Assessment Bulletin* (RAB) which contained a set of guidelines to govern all risk assessments and included technical standards for all federal agencies to use when conducting risk assessments, as well as other scientific documents. The OMB guidelines would apply to risk assessments conducted as part of issuing or revising health, safety and environmental rules, as well as important scientific studies. OMB asked the National Research Council (NRC) to review the document after its release. NRC suggested the Bulletin be withdrawn completely.

The NRC defined RA as "the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations." There are components to conducting a public health RA: hazard identification, dose-response assessment, exposure assessment, and risk characterization.[5] Even without knowing the scientific definitions of these terms, it's clear from the definition and its elements that a risk assessment is an evaluative process.

In its review of the RAB, the Council found that OMB's new definition of risk assessment was "too broad and in conflict with long-established concepts and prac-

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[4] Panel 4: A PRESIDENTIAL REVIEW OF RULE-MAKING: REAGAN TO BUSH II. Part of a symposium on "Presidential, Congressional, and Judicial Control of Rule-making," conducted at the Congressional Research Service on September 11, 2006 as part of the Administrative Law project of the Subcommittee on Commercial and Administrative Law of the House Judiciary Committee.

[5] National Research Council. 1983. *Risk Assessment in the Federal Government: Managing the Process.* Washington, DC: National Academies Press. This publication established the parameters for using RA.

tices." The *Bulletin* defined a risk assessment as a document instead of a process and the goals outlined, when considered together, indicated "that a risk assessment should be tailored to the specific need for which it is undertaken." The emphasis, according to the NRC evaluation, was on efficiency over quality and stated that the goals outlined did not "support the primary purpose of the bulletin—to enhance the technical quality and objectivity of risk assessments."

The report also recommended that OMB leave technical risk assessment guidelines and standards to each federal agency because one size does not fit all when it comes to risk assessments. The Council stressed concerns over "the likely drain on agency resources, the extended time necessary to complete risk assessments that are undertaken, and the highly likely disruptive effect on many agencies."

As OMB has done with other regulatory tools, the risk assessment approach called for in this release would have created unnecessary delays in the rule-making process by adding to the already cumbersome process that OMB oversees. The ability of government agencies to protect the public would be compromised by attempts to manipulate science and the risk assessment process. For example, the proposed standards called for the use of central estimates or tendencies instead of statistical ranges. Using this approach puts the most vulnerable populations, who fall outside these "central estimates," at risk in some analyses.

The rebuke by the NRC is one of the strongest commentaries issued on the trend over the last six years to centralize power over the regulatory process within OMB and move it away from agencies responsible for protecting health, safety and the environment. The Administration has consistently used regulatory tools like RA to manipulate science for its own ends, attempted to impose a one-size-fits-all framework on the agencies' use of these tools, and has shifted the criteria for defining when regulations are necessary away from a health or safety problem and toward market-based criteria. The strongly-worded NRC evaluation should provide a Congress interested in executive oversight with a strong example of the dangers of this regulatory trend.

C. Peer Review

As happened with the two tools described above, OMB developed a bulletin establishing government-wide requirements for scientific peer review. The *Final Information Quality Bulletin for Peer Review* was issued December 2004 after OMB took comments from the public regarding a proposed bulletin that was issued in April 2004. OMB again attempts a one-size-fits-all approach that doesn't consider different agency functions and expertise required to implement legislation. In the final bulletin, OMB asserts that its authority for the peer review policies is implied in the *Information Quality Act* and OMB's general authorities. None of the laws or executive orders referenced provide any specific instructions on peer review. No new authority is referenced by the agency and OMB did not seek any clarifying or supporting language from Congress.

In OMB Watch's comments on the proposed bulletin, we argued that OMB had not identified a peer review problem that justified this government-wide approach. OMB implied that a problem had been identified and defined by citing several studies and reports. However, none of these documents actually claim that an overarching problem or failure of peer review policies has occurred at federal agencies. Nor do the studies recommend the establishment of uniform requirements for scientific peer review. Instead, the referenced materials address the importance of peer review, the need for changes at certain agencies, or types of reviews. Yet, without a clear understanding of any problem in peer review standards, OMB finalized these policies assuming they will do more good than harm.

OMB granted itself an oversight role in the peer review process. OMB has never overseen peer review and holds very little scientific or peer review expertise—only a handful of recently-hired scientists. This grant of authority involves OIRA personnel in the technical and scientific discussions that often lead to a pre-rule-making process. This part of the regulatory process is already dominated by OIRA's gatekeeper function by which it develops acceptable agency rule-making submissions even before the public process.

OMB is a political office working directly for the Administration, not an unbiased scientific office. Yet, the agency places itself in the role of supervisor for implementing scientific peer review. OMB Watch recommended oversight authority to an objective scientific body, such as the National Academy of Sciences or an interagency review panel.

In the final peer review bulletin, OMB solidified its new oversight role for scientific peer review. OMB has the authority to grant exemptions, approve alternative peer review processes, and designate information for stricter review requirements. The final proposal also adds a stipulation that all federal agencies submit an annual

report to OMB detailing the use of peer review for the fiscal year. OMB Watch continues to believe that the bulletin grants far too much influence over the scientific peer review process to the politically motivated offices of OMB and the Office of Science and Technology Policy. Such power would enable an administration to easily influence peer reviews and in turn, the rule-makings that follow.

For the most important peer reviews, OMB created a double standard in which agency employees, who may peer review more basic information, are essentially barred from serving as reviewers. However, experts associated with affected industries are allowed to serve as peer reviewers with only a requirement that their affiliations be disclosed. Highly influential scientific information has much stricter peer review requirements, and OMB explicitly states that government employees should rarely be used as reviewers. The final proposal bans any experts from the sponsoring agency from reviewing information, but makes an exception for the "rare situation in which a scientist from a different agency of a Cabinet-level department other than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere." The unequal standards for private sector scientists remains, but the final bulletin instructs agencies to "consider barring participation by scientists with a conflict of interest."

The peer review process outlined in the final bulletin creates delay by excessive bureaucratic information requirements and certifications, and rounds of public comments. While we generally support providing public access, the very definition of a peer review is to collect assessments from experts. Adding repeated public comment periods is inappropriate for peer reviews and can only result in delaying important research.

D. Federal Advisory Committees (FAC)

There are many instances during the Bush Administration in which candidates for advisory panels have been passed over, or members replaced, or resigned. While it is common for new administrations to replace members of these committees, there is a trend towards making sure that those people who might disagree with the Administration's opinions are not appointed. The scientific community has often argued that by appointing people from the regulated industries as members of these committees, as the Bush Administration has done consistently, the advice the committees offer to an agency might create real dangers to public health and safety.

In the fall of 2002, a series of reports and articles began to be published charging the Administration with manipulation of these committees to assist hazardous substances manufacturers especially.[6] According to DefendingScience.org, a website of The Project on Scientific Knowledge and Public Policy,

> Groups accused the Bush Administration of manipulating activities in two federal committees advising the Centers for Disease Control and Prevention's National Center for Environmental Health (NCEH).
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> - Several well-respected scientists were dropped from the Pediatric Lead Poisoning Prevention Panel. Nominees suggested by staff scientists at CDC were rejected and replaced by individuals who later reported that the lead industry had contacted them initially to ask if they would be willing to serve on the committee.
> - Scientists employed by the chemical industry or industry advocacy groups, including the Heritage Foundation and the Annapolis Institute (established in 1993 by the National Association of Manufacturers to challenge EPA proposed regulations) replaced 15 of 18 renowned university-based scientists on the advisory committee to the Director of NCEH.

We've begun to see more resignations by respected scientists as these FACs have become more politicized. For example, last October, three of the fifteen members of the EPA's National Pollution Prevention and Toxics Advisory Committee (NPPTAC) resigned because they felt major problems with the *Toxic Substances Control Act* were not being addressed due to industry influence.

The impacts of this political approach to using FACs are real dangers to public health, safety and the environment. One example was provided in the February 6, 2007 testimony before the Senate Committee on Environment and Public Works of

[6] David Michaels, Eula Bingham, et al. "Advice Without Dissent," *Science,* Vol. 298, 25 October 2002. p.703. (*www.sciencemag.org,* or *http://www.defendingscience.org/public_health_regulations/upload/Advice-Without-Dissent.pdf*).

Dr. John Balmes, testifying on behalf of the American Lung Association.[7] The focus was on the changes EPA has made to the scientific review process for the National Ambient Air Quality Standards (NAAQS). EPA's Clean Air Scientific Advisory Committee (CASAC) participates in the review process of these standards. The review was a multi-step process the end of which was a Staff Paper reviewed by CASAC and open to public comment. According to Dr. Balmes testimony, " [m]any regard the preparation and finalization of the Staff Paper, which is done by EPA's scientific staff, as the most crucial step" because it is the final analysis of the scientific information on which standards are based. It is not a political process.

According to Dr. Balmes testimony:

> It is the elimination of the Staff Paper that we fear will lead to the diminishment of science in the standard setting process. The staff paper is to be replaced with a "Policy Assessment" which according to a memorandum by EPA's Deputy Administrator Peacock, "reflect the Agency's views, consistent with EPA's practice in other rule-makings." However, the EPA does not set standards exclusively based on the protection of health using the latest scientific research in any other rule-making. In sum, a unique standard demands a unique process, not EPA's "usual" practice. We believe the elimination of the Staff Paper is being done precisely because the science underlying protection of public health from air pollution is in conflict with what policy-makers in EPA want to do in the implementation of the *Clean Air Act.* The elimination of the Staff Paper will make it easier for policy staff to fuzz the lines in public health protection and present the basis for alternative standards and the alternatives themselves in a way that favors the outcomes they are seeking rather than what the science says is needed. Substituting an Advanced Notice of Proposed Rule-making for the Staff Paper will put policy make[r]s (sic) at EPA and the White House in the driver'[s] (sic) seat by enabling them to review and edit before it is reviewed by CASAC and the public.

The process has been specifically influenced by the American Petroleum Institute which suggested the Staff Paper be replaced with an Advanced Notice of Proposed Rule-making, which the EPA has adopted. And the lead industry recommended that the Staff Paper be replaced by a new Policy Assessment which argues that lead should be eliminated as a criteria pollutant.

This is one example of the growing influence of regulated industries in the rule-making process. Like the tools discussed above, FACs specifically, and the processes in which they are used, are being manipulated to achieve results desired by political considerations, not science, health, safety, or environmental protection.

E. Information Quality Act

The final issue I would like to address briefly is the *Information Quality Act* (IQA), or as it is often called, the *Data Quality Act* (DQA). This is an issue in the discussion of manipulation of regulatory tools because the guidelines issued by OMB regarding the use of the DQA has led to delays in the promulgation of public protections through challenges to the science agencies rely on to fulfill their mandates.

The DQA allows challenges to the information disseminated by agencies that can dilute, dismantle and remove essential pieces of the scientific information that go into creating a body of scientific knowledge. OMB published a report in 2004 evaluating the first year of implementation of DQA, a report that OMB Watch criticized as "inaccurate," "misleading," and "flawed." OMB understated the number of challenges, the source of those challenges (mostly industry), and drew conclusions about the impact of the DQA without the data to support its conclusions. OMB Watch's analysis shows that the Act has had a significant impact on agency actions, yet the law was added as a last minute rider without Congressional hearings.[8]

A report issued by the Congressional Research Service (CRS) calls for oversight and investigation of the impacts of DQA, a call OMB Watch argued for in our report as well. CRS recommends

> either Congress or OMB could better define the scope of the act or the issues to be included in any future report. Clarification could also be provided regarding whether correction requests that the agencies determine to involve issues outside the scope of the IQA (e.g., a challenge to the minutes of a federal advi-

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[7] Dr. John Balmes testimony before the U.S. Senate Environment and Public Works Committee, February 6, 2007. Available at *http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=78a52250-802a-23ad-4274-59a54b06a447*

[8] OMB Watch. *The Reality of Data Quality Act's First Year: A Correction of OMB's Report to Congress.* July 2004. Available at *http://www.ombwatch.org/info/dataqualityreport.pdf.*

sory committee meeting) should be included in a report that is supposed to list correction requests under the act.[9]

III. Congressional Action

OMB Watch has several concerns about the trends in the regulatory process that have occurred over the last few decades. Societal problems have become more complex and their solutions are often less obvious and straight forward than, for example, a command and control approach. The role of the federal government has become more limited in its perspective of what is appropriate for government action. Responsibility has increasingly devolved to the states, or been the target of privatization. We believe that the time has come to change this limited government perspective to one in which the government plays a more positive role in protecting health, safety, environmental and civil rights safeguards. A major part of this movement to positive government must be a focus on the regulatory process.

The Bush Administration has further reduced the Federal Government's general welfare protections by putting special interests' concerns above the general public's concerns. The problems outlined in this testimony have eroded the government's role in public protections. They have delayed, diminished or destroyed regulations that agencies are mandated to promulgate. There has been a sustained attack on scientific integrity—on the quality of scientific information, on the scientific expertise of agency professionals, and on the integrity of the scientific process. The tools have been manipulated and the executive order amendments just issued, coupled with the good guidance practices bulletin, have further established control of the regulatory process in the executive branch, and OIRA especially, at the expense of both congressional power and agency discretion.

The real loser, however, is the public. The regulatory process is highly partisan and politicized. In the end, less regulation means less protection. Instead of a regulatory "cop on the beat," we have none. Instead of addressing regulatory gaps, we operate based on whether these gaps have political consequences. Unfortunately, now government doesn't act until there is national news about people being hurt or, in the case mine workers, dying. If you are parents, you don't want to gamble that the weekend barbecue results in your child becoming ill or dying from E. coli. The point is, there are real consequences from these actions and inactions. Our government should be doing more, not less, to protect the public. The amended E.O. moves in the wrong direction.

Every year, more than 40,000 people die on our nation's highways. Food borne illnesses kill an estimated 5,000 and sicken 76 million. Nearly 6,000 workers die as a result of injury on the job, with an additional 50,000 to 60,000 killed by occupational disease. And asthma—linked to air pollution—is rising dramatically, afflicting 17 million, including six million children.

There is real danger to our constitutional system from this arrogation of power. Equally significant, in our opinion, is the real danger presented to the American public from the delay or refusal to regulate dangerous activities. I want to leave you with just one example of the danger.

The *Transportation Recall Enhancement, Accountability and Documentation (TREAD) Act,* passed by Congress in November 2000, required that "Not later than one year after the date of the enactment of this Act, the Secretary of Transportation shall complete a rule-making for a regulation to require a warning system in new motor vehicles to indicate to the operator when a tire is significantly under inflated. Such requirement shall become effective not later than two years after the date of the completion of such rule-making."[10]

The National Highway Transportation Safety Administration (NHTSA) determined that a direct tire pressure monitoring system should be installed in all new vehicles. OMB sent a return letter to NHTSA, after meetings with the auto industry, deciding this action was an inappropriate one, claiming its cost-benefit calculations provided a basis for delaying a requirement for direct systems. The final rule, issued May 2002, would have allowed automakers to install ineffective Tire Pressure Monitoring Systems (TMPS) and would have left too many drivers unaware of dangerously under-inflated tires. NHTSA was sued because its final rule would have allowed manufacturers to choose to install either an effective (direct) system or an inferior (indirect) system. In August 2003, the U.S. Court of Appeals for the Second

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[9] Congressional Research Service *The Information Quality Act: OMB's Guidance and Initial Implementation.* September 17, 2004. p. CRS–18. Available at *http://www.defendingscience.org/public_health_regulations/upload/Congressional-Research-Service-Information-Quality-Act-Report-2004.pdf*

[10] Public Law 106–414, The *Transportation Recall Enhancement, Accountability and Documentation Act,* Nov. 2000. Section 13.

Circuit ordered NHTSA to rewrite the rule because NHTSA acted in an arbitrary and capricious manner by writing a standard that would allow installation of a clearly faulty (indirect) system.

In July 2004, the groups that had sued NHTSA returned to court because the agency had not issued a revised rule. In April 2005, NHTSA finally issued a rule requiring automakers to install tire pressure systems in all new passenger cars and trucks by the 2008 model year, beginning a phase-in with 2006 model year vehicles. The new rule, however, still does not meet the requirements set by Congress. Although better systems exist, the TPMS could allow tires to be 30 percent below proper inflation before the alert is provided, costing approximately 150 lives and countless injuries each year. In June 2005, Public Citizen, the Goodyear Tire & Rubber Company, Bridgestone Firestone North American Tire, Cooper Tire & Rubber Co., Pirelli and the Tire Industry Association, filed suit in the U.S. Court of Appeals for the District of Columbia, arguing that the new rule is inadequate and should be overturned. Tire pressure alert systems regulations that were required by law to be in place by the end of 2003 have, as the tire manufacturers legal action implies, not been adequately developed.[11]

So what can Congress do address this process? First, if Congress concurs that the amendments to the Executive Order are as bad as we believe they are, it should act. Here are three areas to explore.

- Congress should explore the legality of the Executive Order amendments and their implementation.
- OIRA will need to provide guidance to agencies on implementing the market failure criteria. Congress could provide much needed oversight on this guidance to ensure OIRA does not create new standards or irresponsible requirements on agencies.
- Congress has the ability to alter the implementation of these amendments through a variety of vehicles, including the appropriations process. Congress should take a hard look at limiting agencies' and OIRA's spending on the specific elements of the amendments.

Second, we believe it is time for the debate over regulatory policy and process to turn toward the real need to increase public protections not protect special interest access and influence. Because this regulatory process has real consequences for our health and safety, Congress should explore legislative actions that put the regulatory presumption on safety first. Why should products and substances be approved for use before they have been determined to be safe? Why should the economics of regulation be the overriding, to the point of being nearly determinative, consideration to the exclusion of protecting the vulnerable populations like the elderly, the frail, children, and minorities exposed to flawed siting processes? Government and businesses have a responsibility to the public to uphold their parts of the social contract. Congress can lead the way by providing its critical oversight responsibilities and considering legislative proposals that renew the Federal Government's protection of the general welfare.

Thank you, Mr. Chairman, for providing me this opportunity to appear before you. I'm happy to respond to Members' questions.

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[11] For another example of the danger to the public from regulatory manipulation, see the testimony of John B. Stephenson, Director of Natural Resources and Environment, GAO, before the Senate Committee on Environment and Public Works, February 6, 2007. Available at *www.gao.gov/cgi-bin/getrpt?GAO-07-464T.* The summary findings read:

> Although we have not yet completed our evaluation, our preliminary observations indicate that EPA did not adhere to its own rule-making guidelines when developing the proposal to change TRI reporting requirements. We have identified several significant differences between the guidelines and the process EPA followed. First, late in the process, senior EPA management directed the inclusion of a burden reduction option that raised the Form R reporting threshold, an option that the TRI workgroup charged with analyzing potential options, had dropped from consideration early in the process. Second, EPA reviewed this option on an expedited schedule that appears to have provided a limited amount of time for conducting various impact analyses. Last, the decision to expedite final agency review, when EPA's internal and regional offices determine whether they concur with the final proposal, appears to have limited the amount of input they could provide to senior EPA management.

Appendix:

Undermining Public Protections

PRELIMINARY ANALYSIS OF THE AMENDMENTS TO
EXECUTIVE ORDER 12866 ON REGULATORY PLANNING AND REVIEW

On January 18, President Bush issued amendments to Executive Order (E.O.) 12866, which further centralize regulatory power in the Office of Management and Budget (OMB) and shift it away from the federal agencies given this power by legislative enactments. Among the changes to the E.O.:

- It shifts the criterion for promulgating regulations from the identification of a problem like public health or environmental protection to the identification of ". . .the specific market failure (such as externalities, market power, lack of information). . .that warrant new agency action."
- It requires guidance documents to go through the same OMB review process as proposed regulations before agencies can issue them.
- It also requires "significant" guidance documents (those that are estimated to have at least a $100 million effect on the economy, among other criteria) to go through the same OMB review process as "significant" regulations.
- It makes the agencies' Regulatory Policy Officer a presidential appointment and gives that person the approval authority for any commencement or inclusion of any rule-making in the Regulatory Plan unless specifically authorized by the agency head.
- It requires each agency to estimate the "combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities," which will be overseen by the Regulatory Policy Officer.

By-Passing Congress With New Policies

Through amending the regulatory process, the President is institutionalizing an anti-regulatory approach by using a market failure criterion in place of actually identifying threats to public health and safety. It diminishes standards Congress may have required agencies to use, such as the best control technology, by elevating a new market failure standard that Congress never required. This standard has been advocated by Susan Dudley, Bush's current nominee as administrator of the Office of Information and Regulatory Affairs (OIRA). Dudley's extreme views on the use of free market standards were well-documented during her failed confirmation last year. Despite the failure to confirm her, the Administration has used the Executive Order as a backdoor means to implement the Dudley philosophy.

The market failure criterion is yet another layer added to the agency analysis. The agency must comply with the statutory criteria (such as best available technology) as well as an analysis demonstrating market failures. If the agency meets OMB's standards for assessing "whether any new regulation is warranted," then the agency must also comply with other standards in the E.O., including cost-benefit analysis.

This new standard decidedly favors the regulated community and places yet another hurdle for agencies to issue regulations in pursuit of protecting the public.

More White House Control; More Delay

By requiring agency guidance documents to come under OIRA review, and to treat "significant" guidance in the same way as "significant" regulations, the E.O. amendments will lead to further delay in providing information to the public about compliance with regulations, as well as with general guidance on agency policies.

It may be true that more and more agencies are using guidance as a means of avoiding the regulatory process. But that should be a signal to Congress and the public that the rule-making process is seriously flawed. Agencies are looking for faster ways of doing their job and have turned to guidance. The solution is certainly not to require guidance to go through the same regulatory process that agencies were trying to avoid in the first place.

In the end, this will simply result in more delay and more White House control over the substantive work of the agencies. It will inevitably lead to a usurpation of agencies' powers.

The Foxes Controlling the Hen Houses

The Bush Administration has regularly appointed industry representatives or allies to oversee agency regulatory activities. Often this has been dubbed "foxes in the hen house." The E.O. amendments add a new dimension by having the foxes control the hen houses.

The amendments require each agency to have a Regulatory Policy Office run by a political appointee and that "no rule-making shall commence nor be included" for consideration without the political appointee's approval. This will further politicize the rule-making process and provide more White House control over the agency rule-making process.

A similar approach was attempted by President Reagan through his E.O. 12498, the Regulatory Planning Process, which was issued January 4, 1985. Under E.O. 12498, agencies were to get approval from OMB prior to starting a rule-making—a pre-rule-making review. Many in the business community thought this would be a wonderful approach for choking off agency ideas before they ever really got going. That approach, however, proved too cumbersome and difficult to administer; in short order, it failed.

The new Bush E.O. amendments have the same objective, but put the choke-hold in the agencies, instead of at OMB. To ensure that the process works, OMB grants authority to these new political appointees to be the eyes and ears for OMB.

Laying the Groundwork for a Regulatory Budget

The E.O. amendments also require regulatory proposals that are to be submitted to the Regulatory Policy Officer to include "aggregate costs and benefits" during the calendar year. Most experts agree that aggregating all costs and benefits is like comparing apples and oranges—and in the end has little value except to create large numbers intended to scare the public.

Another possible reason to require such information is to begin laying the groundwork for establishing a regulatory budget. This concept, proposed by conservatives since the Reagan Administration, has been criticized by Congress and never approved. Yet the amended E.O. begins to move in this direction.

Pre-Rule-making Review

The amendments to the E.O. allow OIRA to play an active role during the pre-rule-making stage when agencies are formulating annual plans for regulatory activities. By having OIRA involved in agencies' planning process, OIRA can quash any contemplated regulatory or guidance issues before they get proposed for the Regulatory Plan. Under the amended E.O., OMB can now engage the agency, along with other government personnel (as provided for in one amendment), in reaching a "common understanding" on regulatory efforts.

Conclusion

The revised Executive Order that results from these amendments is a further threat to public protections from an administration committed to elevating special interests over public interests. It codifies regulatory delay, further removes agency discretion over legislative implementation, and centralizes control over the regulatory process into a small executive office. It substitutes free market criteria for the public values of health, safety, and environmental protections, and substitutes executive authority for legislative authority.

We can only speculate as to why the President has issued these amendments at this time in his presidency. With Congress now in control of Democrats, it is unlikely that further anti-regulatory efforts will be supported or ignored by a compliant Congress. It is a surprising action to take in light of the Dudley nomination now pending before the Senate. It may be an admission by the Administration that the nomination is not likely to succeed, and that the President has decided to advance the Dudley philosophy through the back door.

Prepared on January 18, 2007

BIOGRAPHY FOR RICK MELBERTH

Rick joined OMB Watch in November 2006 as the Director of Federal Regulatory Policy, the program which works to protect and improve the government's ability to develop and enforce safeguards for public health, safety, environment, and civil rights. He directs all activities related to policy advocacy, analysis, research, monitoring, and public education. Rick comes to OMB Watch from Vermont Law School where he was Director of Internal Planning and formerly the Associate Director of the Environmental Law Center. He helped design the curriculum and taught courses in the Master's program.

Rick has written several pieces about decision-making in government and environmental issues during his academic career and while working as an independent consultant and policy analyst. He started his own used and rare book business which he ran for more than a dozen years. He also worked in the solid waste management field as the manager of a solid waste division and a program to implement a waste-to-energy facility in county government in Ohio. This led to the opportunity to co-author a book for local governmental officials, *Decision-making in Local Government: the Resource Recovery Alternative.*

Rick completed his doctorate in public administration and public policy at the University of Cincinnati in 1982. His Master of Environmental Science (M.En) and AB in political science are from Miami University.

DISCUSSION

Chairman MILLER. I thank all of you.

There are only two Members here, so the rules do allow waiving the five-minute limits to some extent. Mr. Sensenbrenner has graciously offered to help teach me how to be a Chairman.

Mr. SENSENBRENNER. That is called push the button when somebody starts speaking.

Chairman MILLER. I am sorry. Okay.

Mr. SENSENBRENNER. I do have questions. It won't last five minutes.

Chairman MILLER. Actually, so did I.

Mr. SENSENBRENNER. Okay. You are the Chairman. You go first.

ROLE OF OIRA

Chairman MILLER. All right.

Mr. Kovacs, in Mr. Vladeck's testimony, his written testimony, he said that the role of OIRA was a one-way ratchet. It always resulted in weaker regulations. Dr. Melberth cited one example, the gauge on tire pressure, where OIRA had—their role had resulted in a weaker regulation that was overturned by the courts.

Can you give examples of when agencies have sent proposed rules to OIRA in the last six years, during the Bush Administration, where the Bush Administration has sent back the rule, and said this is not tough enough? We really need to do more to protect public health, to protect safety, to protect the environment, to protect privacy rights, or civil rights, or whatever. Can you cite examples of when OIRA has sent regulations back to the agency from which they came, and said make it stronger?

Mr. KOVACS. I don't have any list of the rules that they have sent back to the agencies, and I don't even know that one is public. I do know that the first year and a half, when John Graham was head of OIRA, he did send a number of rules back, and I believe one of them was the particulate matter rule. So the first couple of years, about 18 months, he did it, and then, for some reason, it all

of a sudden stopped. They weren't sending as many back, but it was a standardized process during that time period.

Chairman MILLER. Ms. Katzen, are you aware of circumstances in the last six years that OIRA has sent regulations back and asked the agency to toughen them up?

Ms. KATZEN. No, I am not. The return letters are public, because they are posted on the website, and I think OIRA has, under the Bush Administration, increased the transparency by greater use of the website for that purpose. I have read all of the return letters, and I have not seen any requiring, requesting, entreating greater protection or more stringent, achieving better benefits.

Chairman MILLER. Mr. Vladeck, you obviously want to answer.

Mr. VLADECK. The statistics are public, and in fact, Curtis Copeland of the CRS has published an article in the 33 Fordham Urban Law Journal which discusses all of the statistics which are public since 1994, including those from 2000 to 2005. You will see there are an awful lot of return letters. There are a lot of changes made. One of the categories is "consistent with change," those are changes pushed by OIRA, and the numbers are quite large, and I look at the return letters, as does Ms. Katzen, I have never seen one returned to beef up the rule, in a way that would protect the public health.

TRANSPARENCY PROVISIONS

Chairman MILLER. Okay. Ms. Katzen, you obviously played an important role in the Clinton Administration in drafting the original Executive Order 12866, and you spoke a moment ago of transparency in the role of OIRA, and I understand that transparency was part of that Executive Order. It required communication between the agencies and OIRA to be public, subject to a FOIA request. It required, as I understand it, any changes, the return letters, to be public as well, and communications between OIRA and outside agencies, who are urging a change in the rules, whether it is entirely proper urging of an industry to say this is unworkable, but it made those communications public, so that the public could decide whether any changes that OIRA made were appropriate, or an appropriate response to legitimate concerns raised by those most familiar with what the agencies would do, what the regulations would do, or whether it was caving to pressure.

Is that, essentially, are those the——

Ms. KATZEN. There were a number——

Chairman MILLER.—transparency provisions?

Ms. KATZEN. Yes. I mean, Mr. Kovacs talked about going back to Richard Nixon, and I do discuss this in my written testimony, President Reagan took a dramatic step forward, and that was highly controversial, because it was opaque, at best. It was just not transparent.

When we drafted 12866, we were highly sensitive to that, and wanted to make sure that we met that one head-on. In fact, it was in part because Members of Congress had spoken out so forcefully, calling for openness and accountability, that we responded by including the provisions that you mentioned in the Executive Order. That is the role that I think Congress should have, which is to make sure that the executive is aware that there is—are two

branches of government involved, since it is the Congress that delegates to the agencies in the first instance the authority to regulate.

The other comment, if I may, sir, the thought that we, that this is simply a logical progression from what the Clinton Administration did cannot be substantiated. I was there for six years. I never saw a guidance document. I never asked to see a guidance document. The concept that this is just business is usual, and you know, President Clinton did it, he might as well do it, too, just couldn't be further from the truth.

Chairman MILLER. Thank you. I have more questions, but I will save them for a later round. Mr. Sensenbrenner.

OUTSIDE COMMENT ON E.O. 12866

Mr. SENSENBRENNER. Thank you very much, Mr. Chairman.

First, let me put on the record that the Executive Order that President Bush issued amending Executive Order 12866 was signed on January 18, 2007, just 28 days ago. So, the process that we are talking about and the issuance of the regulations are all done pursuant to Clinton's Executive Order, because I don't think there have been any major regulations that have been issued as a result of the amendment.

The amendment of the President's most recent Executive Order talks about process. It doesn't talk about the bottom line of the regulation, and I guess I would kind of like to find out why three of the four witnesses did not send any—in any comments relative to the amendment when it was under consideration.

Ms. KATZEN. If I may, Executive Orders are not typically put out for notice and comment. The comments that were filed were filed on the Good Guidance document, rather than on the amendment to the Executive Order.

Mr. SENSENBRENNER. I stand corrected on that, but where the comments were solicited and received, Mr. Kovacs had some input on it, but none of the other three of you did, and why is that?

Ms. KATZEN. He represents an entity that is an interested participant. I am an academician, and I write scholarly articles, unless I am asked to testify in Congress, I——

Mr. SENSENBRENNER. Well, I think you are really interested in that, given what I have heard you say.

Ms. KATZEN. I am very interested, yes, sir.

Mr. SENSENBRENNER. Okay. But you didn't comment. Now, Mr. Vladeck.

Mr. VLADECK. The two organizations with which I am affiliated did comment, Public Citizen and OMB Watch. I am on the Board of Directors of OMB Watch, and I still have a relationship with Public Citizen. They both did comment.

I did not personally comment on the guidance——

Mr. SENSENBRENNER. Dr. Melberth.

Mr. MELBERTH. Mr. Sensenbrenner, we did submit comments on the proposed GGPB bulletin, under Citizens for Sensible Safeguards. It is signed by members of the coalition that we lead, and my predecessor as Director of Regulatory Policy was one of those signees.

Mr. SENSENBRENNER. Yeah. Now, you know, with respect to market failure, using market forces the *Regulatory Reform Act* that was signed by President Clinton, and was a part of the Contract With America, and passed by Congress in 1995, did require cost-benefit analyses to be applied during the regulatory process.

Do you think that was a good idea? I will start with you, Dr. Melberth.

Mr. MELBERTH. Yes, sir. I think cost-benefit analysis is an appropriate tool to be used, not——

Mr. SENSENBRENNER. Mr. Vladeck.

Mr. MELBERTH.—as a——

Mr. VLADECK. I don't believe centralized review is a good idea to begin with, and requiring all agencies to do cost-benefit analysis, even for significant rules, in my view is a bad idea.

Mr. SENSENBRENNER. Okay. Ms. Katzen.

Ms. KATZEN. I am a proponent of cost-benefit analysis as an input to decision-making, not as dispositive of the outcome.

Mr. SENSENBRENNER. Now, do you think that the cost-benefit analyses should be just as transparent as some of the other things that you have testified on, so that the public and perhaps the Congress can see if there is a proposed regulation that it has about this much benefit at that much cost?

Ms. KATZEN. Yes, and in fact, during the Clinton Administration, there were many occasions when the cost-benefit analysis was larger, more paper, more analysis, than actually the rule-making, to provide the kind of information that people should have.

It is also very important to emphasize that agencies are not free agents. They are able to regulate only because Congress has delegated them the power to do so.

Mr. SENSENBRENNER. But the agencies are——

Ms. KATZEN. And we have——

Mr. SENSENBRENNER.—headed by someone who is appointed by the President of the United States.

Ms. KATZEN. Absolutely. All I am saying is that we had several instances, while I was the Administrator of OIRA, where, on the basis of a cost-benefit analysis, we saw that the costs were larger than the benefits, but that the Congress had given us no discretion, and that we had to proceed. In at least one instance, we made that finding loud and clear, and sent a letter to the Congress saying please amend the law, so we don't have to do that. And Congress did.

Mr. SENSENBRENNER. It does work.

Ms. KATZEN. Yes, how it should work.

Mr. SENSENBRENNER. Yes. I yield back the balance of my time.

Chairman MILLER. Thank you, Mr. Sensenbrenner. Mr. Baird.

Mr. BAIRD. I thank the Chairman.

First of all, Dr. Melberth, you were going to continue your thought. I would like to ask you if you would like to do that. Earlier, you were asked a question by Mr. Sensenbrenner, and gave a partial answer, and were in the middle of continuing. You care to elaborate?

Mr. MELBERTH. Thank you, Mr. Baird.

I do think cost-benefit analysis is a good thing to have as part of the decision-making process. I have several problems with cost-benefit analysis, but however it is used, it should only be one aspect of that decision-making process. It should not be dispositive. It should not be the driving mechanism, in my opinion, in that decision-making process, which does not, if you use cost-benefit analysis as dispositive, include any of the non-quantifiable aspects that are so often underestimated in cost-benefit analysis.

Thank you, sir.

MARKET FAILURE PROVISIONS

Mr. BAIRD. I appreciate your expansion on that point.

I am a little puzzled by one of the core issues here, and it has to do, this market—as a market process. Apparently, the issue is that we don't need regulations if the market would already regulate itself, and I am just puzzled, I am completely puzzled about how one operationalizes that. I don't know that the marketplace in general, as currently structured, incentivizes many industries to engage in responsible behavior, except fiduciary responsibility to their stockholders. I am not saying that is a bad thing, but I don't think the market intrinsically is designed to protect workers, public health, environmental issues, so if any of you care to enlighten me about what the heck this means, and if it is the metric by which OMB or other executive branch offices are going to evaluate regulations, I would sure like to operationalize that metric.

Ms. KATZEN. You want me to try this one?

The concept is that regulations will be necessary where there is a failure of the marketplace, and the terms that are often thrown around are "externalities," "lack of information," "market power." If you are an agency, and you can demonstrate that there are one of these externalities, market power, lack of information, then you are kind of home free. The point I think some of us were making is that there are often good reasons for regulations that do not involve market failures, where the market can be functioning absolutely the way a market should, and I am thinking of areas such as civil rights or privacy, where market failure is irrelevant to the underlying issue, and there is a need for something to be done.

The way the original Executive Order was drafted, it was an instruction to the agency to identify the problem that you were trying to address, parenthetically, was it attributable to a market failure or something else, close parentheses, and how you plan to fix it. Now, it does tell us about the market failure, and maybe it is a failure of a public institution, and then, go on and worry about the rest of it.

It is a different emphasis on a different syllable. It comes out different, and that is what I am reacting to, I think.

Mr. VLADECK. Well, let me jump in.

The best way to understand the pitfalls of this is just look at the regulation of airbags. Detroit waged what the Supreme Court called the regulatory equivalent of war to forestall regulatory and Congressional action requiring the installation of airbags. So, if you talk about market failure, where exactly is the market failure? People were still buying cars. And even once GM, which was the first company to introduce airbags, started to introduce them, they have

sold them as an add-on, not as part of the car. They were very expensive. And even today, when you have certain kinds of airbags, some of the side curtain airbags, that are, you know, that are not required by federal law, the marketing of them is done in, you know, for the American companies, they are add-ons, they are very expensive add-ons. Now, is the market working?

The introduction of airbags in the United States was delayed for about 15 years because of the battle that the industry fought to keep airbags off the market, and provided that no one was offering them, they weren't suffering any economic consequence. Now, if you look at the new Executive Order, it substitutes the question that was from the Reagan Executive Order, carried forward to the Clinton Executive Order, which is tell us, tell OIRA, why it is you want to regulate. That is all you have got to do.

Now, let me just read you what the new Executive Order substitutes in its place. It says: "Each agency shall identify, in writing, the specific market failure that warrants the new rule." The word "shall" is a word of command. It is not if you feel like it. And so, what this change to the Executive Order does, is it places the lens of the agency and OIRA on market failure. Yes, there is an escape clause. You will hear a lot about that. But it is a substitute for market failure analysis, and OIRA, not the agency, ultimately calls the shots.

Mr. KOVACS. Let me see if I could take a crack at it, because we have talked about market failure quite a few times, and one of the advantages of not being a law professor is the only thing I know is what I read, and what the statement says is: "Each agency shall identify, in writing," as the Professor suggests, "the specific market failure," but then, it says "such as externalities, market power, lack of information, or another specific problem that it intends to address," again, brackets, "including, where applicable, the failure of public institutions, that warrant new agency action, as well as the ability to assess the significance of the problem."

So, it is not just market failure. It is a variety of failures that might occur. I think it goes back to the simple concept that was raised 35 years ago, which is tell us what the problem is, and tell us how you are trying to address it. I don't think we can impute that this is only just market failure, when they give all of that other explanatory language.

Mr. BAIRD. My question is that that sounds nice, but if someone actually wishes to use the language as a smokescreen to push a different agenda, that is where the rub is. And if we're all well-intentioned, sincere, honest, earnest people, with a similar shared value-set and agenda-set, I don't know that there would be a problem.

My concern is does the rewrite, and I think some of the other witnesses seem to be hinting at it, saying pretty directly, the problem is that this new language puts the onus and the decision-making in a different area than it used to be, and that that opens the door for potential shenanigans and actions contrary to the public interest. That is my read of it.

Mr. KOVACS. I guess, you know, there are theoretical ways to look at the regulatory process, and we went over, you know, what it looks like from a small business point of view, but you know, if it were up to the Chamber, you know, we don't just want peer re-

view, we want open peer review, so that we can have all the brilliant minds comment. We want complete transparency, because we think that that is the easiest way to deal with the agencies. Unfortunately, we are in a political situation that the agencies have always opposed that much transparency.

So, I think what you have here is a very practical situation. You have one President of the United States who is responsible for the executive branch of government, and he has to have some management authority. This President has decided, through the Executive Order, and through these guidance documents, that this is the kind of transparency he has.

We participate in that process. Are we happy with it all the time? No. But I don't think you can, as some of the panelists suggest, that there is some manipulation here, or something sinister. The regulatory process is extremely complicated. There are a lot of laws, and a lot of people trying to work this process. All we have ever asked when we go through on these kind of situations is that we have some mechanism, if the problem isn't addressed and assessed, that we can get back into the process. And I think——

MORE ON TRANSPARENCY PROVISIONS

Mr. BAIRD. Mr. Kovacs, I appreciate very much the insight.

If I could ask just one last question. When Vice President Cheney was drafting the energy policy, he invited a number of folks, I think, from oil and gas, to the White House. Many of us were curious as to who those folks were. From what you have just said, the Chamber of Commerce is very interested in transparency. Was it the Chamber's official position back then, and is it now, that the Vice President of the United States should share information about who consulted with him on energy policy?

Mr. KOVACS. Our—well, I don't know about any particular issue, but our policy has always been transparency, and I think there are logs out there, as to who signs it—certainly, when I go over to any meeting over at the White House, I sign in, give my Social Security number, date of birth, and everything else, so that information should be there.

If it were up to me personally, this isn't the Chamber, I mean, I would have all schedules of all public officials open to——

Mr. BAIRD. Well, for the record, then, I would just request that you would report back to this committee on—last year, I had a conversation with your leadership of the organization, and if that is the case, if there is a consistency of value here, that we want open public information, please send us a letter, which we will convey to the Vice President, asking him, on behalf of the Chamber of Commerce, to share the names of the people who helped draft his energy policy.

Mr. KOVACS. I wasn't addressing it to any particular policy. What I said, just from my words, is we think that government in general should be open.

Mr. BAIRD. And I agree with that entirely. I agree with that entirely. What I am saying is it may be a fairly selective belief. If that is your belief, I don't know how many things are more important in this country than our energy policy, and if that is your belief, share that belief with us, and apply it equitably across, not

just to this particular proposed regulation, but equitably across the activities of the executive branch, and we will convey that the Chamber of Commerce formally believes the Vice President of the United States, consistent with this policy of openness advocated by the Chamber of Commerce, shares with the American public the names of the people who developed this energy policy.

Mr. KOVACS. Just so we are on the same page—I am very willing to go back and make that request, just so we are sure it is going to be a general statement. How you use it is completely up to you.

Mr. BAIRD. I will look forward to the statement.

Mr. KOVACS. Well, we would hope that you would extend that to all of the other agencies, and how all of the other rules, like PM and ozone and——

Mr. BAIRD. Right.

Mr. KOVACS.—everything else are made.

MORE ON MARKET FAILURE PROVISIONS

Chairman MILLER. Mr. Kovacs, Mr. Baird, I am struggling to continue to chair this subcommittee meeting without the tutelage of Mr. Sensenbrenner, but we will have time for a second round of questions, although I understand the Judiciary Committee has claimed this room beginning at 2:00.

I did have a couple of questions, before turning to Mr. Rohrabacher, kind of on the doctrine of hot pursuit, about the market failure issue.

Mr. Sensenbrenner said that in 1995, Congress passed and the President signed regulatory reform legislation that did place into law cost-benefit analysis. Mr. Vladeck, you are shaking your head no to that, but does market failure appear in statute? Is that a criterion for the approval of regulations, or for a regulatory agency to act or not to act, that Congress has ever placed into federal law?

Ms. Katzen?

Ms. KATZEN. Not that I am aware of. I think what Mr. Sensenbrenner was referring to was the Unfunded Mandates Act, which refers to an analysis of the costs and the benefits, and there is no mention, no mention of market failure in that, or in SBREFA, the Small Business Regulatory Flexibility Act, which was also passed at that time, nor in the Congressional Review Act, which was another product of that Congress.

So, it is not legislative language, sir.

Chairman MILLER. Okay.

Mr. VLADECK. That is consistent with my understanding, as well. And the Unfunded Mandates Act is a limited statute. It doesn't require cost-benefit analysis across the board.

Chairman MILLER. Mr. Kovacs, do you——

Mr. KOVACS. Again, I am not reading it as just market—as that being the only criteria. I mean, I just don't think the language gets you there.

Chairman MILLER. Okay. Mr. Vladeck, in his written testimony, said that the woman appointed or nominated to be chair or to head the OIRA, Susan Dudley, who I have never met, and I have not read her writings, but—strongly believes that the market seldom fails, that there is almost always a market mechanism that corrects any societal ill.

If we now place into the regulatory framework a criterion, not established by Congress, that is going to be administered by someone who believes, apparently, or according to Mr. Vladeck, almost as dogma that the market seldom, if ever fails, Mr. Kovacs, is that the distribution of authority between the branches of government you think the Framers of the Constitution intended?

Mr. KOVACS. Well, first of all, being—or having worked on the Hill for years, I am a very fervent believer, personally, in the prerogatives of the Congress as a separate branch of government, and the agencies have a Constitutional obligation to implement the laws as you pass them.

And granted, within that, there is some discretion, based on a lot of different factors, whether it be budget or personnel, or how it is, but I am not, you know, I am not here saying market failure is the only criteria. There are other criteria here which I would hope that the agency would recognize.

I am taking a position as I read it that the agency has to identify, because of all of these different conditions, what the specific reason is that they are going to move forward with a regulation, not that it can only be market failure, because obviously, there are reasons you would implement a regulation other than market failure, civil rights, for example.

Chairman MILLER. Okay. Mr. Vladeck, do you wish to address that?

Mr. VLADECK. Yes. Let me just use as an example the upgraded airbag rule, which Ms. Dudley was virtually alone in opposing. As you know, when Congress required the introduction of airbags, it did not set performance standards, and as a consequence, the first generation of airbags were very inexpensive, and not as effective as they should have been.

Congress told NHTSA to go out, and to improve the quality of airbags that are available to the American people. Ms. Dudley's comments opposing the revisions to the airbag standard took the position, quite strongly, that market failure had not been shown by NHTSA, the agency, and therefore, the agency shouldn't proceed.

The reason why I think this is germane is that phrases like "market failure" can mean different things to different people, and if the Administrator of OIRA can block a significant rule, or return a significant rule, because she believes that the agency has not made a case for market failure, it gives OIRA a tool to block important developments to protect the public safety and health.

Chairman MILLER. I do want to preserve time for another round of questions, and that was not one of my rounds, by the way.

Mr. Rohrabacher.

REGULATION AND THE PUBLIC INTEREST

Mr. ROHRABACHER. Thank you very much, Mr. Chairman.

Let us get—this obviously goes to the way we look at things fundamentally, and not—there is a fundamental philosophical issue, and whether—how that philosophy relates to reality, and how it impacts on people's lives, and let me note that people who believe in the market are not just philosophizers, we believe in the end, it means that people's lives will be better off.

Some fundamental questions, then, apply here. We must note fundamentally, that at times, it is difficult to determine exactly what the public interest is. This is not where there is an omnipotent group of people who are commanded by God, who understand exactly what the public interest is, whether or not resources should go, for examples, into airbags, or whether or not resources should go someplace else. And I think it is somewhat of a—to the degree that we are talking about public assets, the air, the water, the soil, then we need to sit down and determine for the public how those publicly held assets will be, you know, will be used, and regulation and certainly government intervention in those areas, is justified. But in terms of how much the public is willing to pay for their safety or something else that they might want, they might want a higher proportion of this, as compared to what the regulators think is best for them. And that is one issue that I would like to throw on the table.

Another thing, let me note that my observation over the years has been that every time that we have people who move forward in a regulatory process, in the name of protecting the general public, quite often, they are influenced by special interest groups, and the more, the further away from the consumer, and the further—where they have choice in the matter, or by elected officials, who are by their very nature, dependent on the voters or the consumers, to approve of the job they have done, once you go to a regulatory approach, it becomes less responsive to the public need, and more responsive to people who can work their way into the regulatory process, meaning people who can hire the lobbyists down here who know the system, and especially, the system that happens in a regulatory process.

So, I just thought I would throw those ideas out. Let me just ask you, maybe if we could have it from both sides of the spectrum here, on your analysis of what I just said, or your reaction.

Mr. MELBERTH. First of all, the use of willingness to pay as a measure of public interest, to determine the relative costs.

Mr. ROHRABACHER. Yeah. A car, you know, may—people may well be willing to spend more money for an airbag in a car, but they may not. It may deter people from buying new cars. It may leave the poor people on the outs, because they don't have any airbags in their cars, and et cetera. So—would—by the way, let us get into that. Would you mandate that all cars be retrofitted with airbags? Isn't that—wouldn't that be something, if you have the public interest—and why don't you do that? You don't do it because there is a cost factor. If there is a cost factor with older cars, why is that cost factor not important with newer cars? So, just a thought. Go right ahead. Be—I am sorry I interrupted you.

Mr. MELBERTH. Well, what I understand by the willingness to pay is the use of that in some kind of cost, economic assessment. And the problem with using that kind of willingness to pay is it puts people in a hypothetical situation of trying to judge the risks that they face.

Mr. ROHRABACHER. Right.

Mr. MELBERTH. That seems to be highly unrealistic, and if you put people in a situation in which they are actually faced with a

danger, a drowning child, are they going to jump and save the child? Of course they are.

Mr. ROHRABACHER. Right.

Mr. MELBERTH. There are those kinds of situations, and yet, you know, the willingness to pay doesn't go anywhere——

Mr. ROHRABACHER. Well, let us go—let us argue a hypothetical—specifically. I have triplets. My wife had triplets. Everybody knows that. And I am a very proud father, and I want those kids safe, and I tell you, I am willing to pay the extra money for the gas to have a big, heavy car, because when my wife goes to the market, I want to make sure if that car is hit, that they are safe. I am willing to pay that extra. But mandating that cars get much more miles to the gallon, and are much lighter, because they have to make it lighter, shouldn't I, as a consumer, be able to do that, rather than have a regulator make that decision for me?

Ms. KATZEN. If I could come at this from a slightly different way.

Mr. ROHRABACHER. Sure.

Ms. KATZEN. I don't have difficulty with the concepts that you are putting on the table. What I think is important is that when Congress legislates, and then when the agency regulates, it take into account all of the different views. That is why the process of rule-making, under the Administrative Procedure Act, Section 553, and in reality, is a very open process. It is a process that features public participation, be it by special interests or by individuals, who can contribute their views, their philosophies, their approaches, their data, their analyses, to the issue.

That is what rule-making is all about, which is why it takes months, sometimes years, to issue rules. The point I was trying to make earlier is that what I find troubling, deeply troubling, is if the process is skewed to come out one way or the other. If the process is neutral, let us hear your thoughts, let us hear your information, we will take into account all of these factors, and we will reach a judgment and be accountable for that judgment, then, I think it is appropriate. But if you have got, as I used the analogy earlier, a thumb or a fist on the scale, and you say we are going to come out one way or the other——

Mr. ROHRABACHER. Yeah.

Ms. KATZEN.—then you have squashed or squelched, or whatever——

Mr. ROHRABACHER. Well—totally legitimate. Obviously, you have made a legitimate point there, obviously.

Mr. VLADECK. Let me try to respond as well, because I think I do disagree with your fundamental premise.

I think it would be, at this point in time, irresponsible for government to permit the sale of motor vehicles, cars, to transport somebody else's triplets without airbags. I think that would be irresponsible, and frankly, you started by saying——

Mr. ROHRABACHER. Would you retrofit it?

Mr. VLADECK. I would——

Mr. ROHRABACHER. Would you demand that all cars be retrofitted?

Mr. VLADECK. I wouldn't, and nor did Congress when it decreed that cars have airbags, make that choice. Because ultimately, your question was, you know, who decides what is the public interest?

You guys do. That is why we pay you the big bucks. And Congress decided that there should be airbags.

Now, the more difficult questions are what kinds of airbags, and how much safety to impose, and those are delicate questions of balancing. There are tradeoffs there. If you want a safer car, all cars are not created equal. If you want to buy the safest car on the market for your triplets, there are better cars and there are less safe cars. And NHTSA has not gotten a mandate from Congress to require the maximum degree of safety no matter what. Those are the difficult tradeoffs that you enlist expert agencies to help you, and what I am concerned about is that the executive branch is handcuffing those agencies in their ability to do the public business.

And let us talk about transparency. One of the odd things about the new Executive Order is the transparency and time limits are not required for guidance documents. OIRA can sit on a guidance document for five years, consistent with this Executive Order. It can engage in all sorts of non-recorded contacts with respect to guidance documents under this Executive Order. This Executive Order goes back to the early days, where OIRA was allowed to conduct a big part of its business in secret, and for someone who cares about openness, transparency, the way the markets ought to work, that is inimical to the way government ought to function.

MORE ON TRANSPARENCY PROVISIONS

Chairman MILLER. Thank you. Thank you, Mr. Rohrabacher. If you would hang around for a minute, you may get another round of questions.

But I want to pursue the discussion that we were just having about transparency, and that I had begun in my earlier round of questions.

Mr. Kovacs, you spoke a great deal about transparency, openness of government, and seemed to take the pro position with respect to that, the position in favor of that. All the—all that Ms. Katzen described about the earlier Executive Order by President Clinton, the transparency, the public availability of documents by—OIRA documents or communications with the agency, their communications with outside parties who are advocating for some change in the regulations, any changes in the regulations, you support all of those, all those transparency requirements?

Mr. KOVACS. Oh, certainly. We have—well, I will go, you know, one step further. We, actually, were probably the primary advocate for the *Information Quality Act,* which is going to, you know, turn everyone sort of bright red here.

But you know, what that says is, is that, what the Congress ordered is that the agencies have to use the most accurate, up-to-date information, and that if the information, if someone in the public believes that the information is incorrect, that they can file a petition to correct the information. Again, you heard the same arguments. This is trying to slow the agencies down, this is trying to put everything in secret.

We have been very clear. We don't believe just in peer review. We believe in open peer review. Just open it up. Why should four or five scientists have a say over what the issue is? So, when you

come to the openness, the only way we are going to get the kind of information in, from the public into the agency is if we know what the agency is doing, and we are able to put it in, and that is what the guidance documents do.

Chairman MILLER. Okay. Thank you, Mr. Kovacs.

Ms. Katzen, under the new Executive Order, under the old Executive Order, OIRA was a gatekeeper, and now, the gatekeeper has a gatekeeper, the public regulatory officers within each agency. All of the openness requirements with respect to OIRA's deliberations, do those apply, under the new Executive Order, to the conduct of the public regulatory officer? What are the requirements for transparency at the agency level for the gatekeeper's gatekeeper, the public regulatory officers?

Ms. KATZEN. Those are not addressed in the Executive Order. Those would be wholly dependent upon the agency's own internal rules for ex parte procedures, for disclosure, for rule-making, as the case may be.

Chairman MILLER. Mr. Vladeck, rather than write a note to Ms. Katzen, do you just want to answer yourself?

Mr. VLADECK. Well, I mean, it is worse than that. I mean, not only does the Executive Order not apply, but the D.C. Circuit, in a case that I helped lose many years ago, it is called Wolfe v. HHS, held that communications between officials at OMB and the agencies, like the regulatory officer, are presumptively not available under FOIA.

So, there is no—as far as I can see, there is no mechanism by which we would be able to see what is going on at that stage of the development process, which is a trouble.

Chairman MILLER. I think every Democratic Member of Congress not in their first term has in their files letters from agencies explaining that FOIA does not reach pre-decisional discussions, internal agency documents, which presumably, the involvement by the NPOs, or——

Ms. KATZEN. RPOs would be.

Chairman MILLER. RPOs, would fall within that exception to FOIA. Mr. Kovacs, do you think the conduct of the regulatory public officers, the RPOs, should be as transparent as the conduct, the involvement of decision-making by OIRA?

Mr. KOVACS. If you are asking me would we support an exempt—would we support removing that exemption from FOIA, it is likely. But we would again, remove it for the entire process. Let me just give you really one example. For years, one of the biggest growth industries that is coming to the United States is nanotechnology. They expect in ten years, for that to be a $1 trillion plus revenue stream for the United States, a huge growth industry.

Well, floating around EPA are some pre-decisional opinions on how EPA is going to regulate nanotech. Well, the business community is putting in an enormous amount of money into nanotechnology, and we sent a FOIA letter, I don't know, six months, eight months ago, and we can't even get a little postcard from them. So, it is a frustration that we all share. But if you are going to do it, rather than, you know, picking on the Vice President, or picking on one—open the process——

Chairman MILLER. Well, looking specifically at the regulatory public officers, who are now going to play an important role. I mean, a great many regulations are never going to make it to OIRA. They will be smothered in the crib, at the agency, by the RPO, and all of the requirements for transparency for OIRA appear not to apply to the RPOs.

Mr. KOVACS. Well——

Chairman MILLER. So, if the agency is making the wrong decision for the wrong reasons, we are not going to know about it. If OIRA makes the wrong decisions for the wrong reasons, we are going to know about it. And now, a great many agents—of the regulations that the professional staff, the permanent professional staff, the experts, the scientists, the researchers at regulatory agencies, are never going to make it past the gatekeeper's gatekeeper, and none of that will be public. Isn't that right?

Mr. KOVACS. I think it would be consistent, to directly answer your question. I think it would be consistent with the policies of the Chamber that the entire—that that part of the entire agency process, as to how a rule is made, should be made public. And it wouldn't start just with the rule, it would start with the information that comes in, the studies that they rely on, the risk assessments that they rely on. That entire process should be open.

And the political officer, the regulatory officer, is only—I am sorry—is only the last person in line. And what I would suggest to you, that if you are going to do that, is that you start with what you know, the EPA at Research Triangle Park does, which is let us look at the risk assessments. What is the basic information, and what we would say is rather than just taking one spot of the record, take the entire record, because then, and that is what the *Information Quality Act* tried to do, it tried to say rather than starting at the end of the rule-making process, which we are all fighting about today, start at the beginning. So—because if the agency uses the wrong information in the beginning, five years before the rule starts, Sally says ten, you know, these processes can take ten years. If you use the wrong information in the beginning, you are going to use the wrong information in the end. So open up the whole process.

TRANSPARENCY COSTS

Chairman MILLER. We really are just about out of time, and I apologize to Mr. Rohrabacher, probably not be able to get to him for a second round of questions.

Ms. Katzen, Mr. Vladeck, Dr. Melberth, do you think the same transparency requirements that apply to OIRA should apply to the internal agency deliberations, of the role of the RPO, whether through changes to the Executive Order, or through statutory change?

Ms. KATZEN. I am not going to answer your question directly, because——

Chairman MILLER. Okay.

Ms. KATZEN.—I spent enough years at OMB to know that nothing is cost-free, and one of the points that Mr. Vladeck made, that I want to underscore, is that the agencies have not only been required to do more analysis, more everything, but they have been

given less funds. And when you say shouldn't things be transparent, even that is not cost-free. Putting up a website and maintaining it takes personnel, takes funds, even if you outsource it, you have got to have a contractor, you have got to update it every 15 days, it takes people, it takes time, it takes talent, and we have seen in the last—when I was at OMB, we had surpluses as far as the eye could see. Now, we don't, and it is coming out of the agencies' budgets, and I think that is a real concern. So, I can't truly answer your question.

Chairman MILLER. Okay. Mr. Vladeck.

Mr. VLADECK. I would agree. I think that you have to make this process transparent.

Chairman MILLER. Okay. Dr. Melberth. Melberth.

Mr. MELBERTH. I would also agree. That is something that OMB Watch has called for in most of these instances. Make this information public. It should be available. It should be accessible.

Chairman MILLER. Mr. Rohrabacher, do you want to have one valedictory question?

Mr. ROHRABACHER. Thank you. I am very happy that when—what year was that, when you were saying we had the surpluses? I——

Ms. KATZEN. 1999. The year.

Mr. ROHRABACHER. Yeah, I remember that. We Republicans were in solid control at that time. You know, here in the House.

Ms. KATZEN. Here.

Mr. ROHRABACHER. Yes.

Ms. KATZEN. Not there.

Mr. ROHRABACHER. Right. There you go. Analyzing stuff. Let me note that, years ago, it was a consensus on global cooling. Now, it is a consensus on global warming. The regulators always—there are things that—trends that could be true or not true, that influence these benevolent and not profit-seeking regulators, that we want to trust our lives to. One, for example, Mr. Chairman, a decision that was made years ago by people, I am sure, with very good hearts, wanting to protect us all, put severe restrictions on DDT, and now, we have tens of millions of people in Africa who have lost their lives because DDT has not eliminated the mosquito population, which is plaguing them instead of us. There are unintended consequences at times, and trendiness, that affects regulators.

I—Mr. Chairman, it doesn't seem to me that we have a real conflict. If you folks are advocating more scrutiny and openness, and focusing on this end of the process, and you have the Chamber of Commerce just saying that it should be transparent all the way through, I don't see a big conflict here, and I have learned—I am sorry I was late. I will read your testimony, but I have already learned quite a bit just from what you have said, and I certainly agree with the idea of transparency and accountability. That doesn't seem to be a big debate here, but it seems a matter of where you are putting your emphasis.

So, thank you very much.

Chairman MILLER. I want to thank everybody. An excellent panel of witnesses, and I think some of you are now going to appear, this has been a warm-up for your appearance before the Judiciary Com-

mittee, and I look forward, for the Subcommittee on Administrative Law, that is looking at the same issue.

And we had earlier tried to have a joint hearing, but were not able to pull off the logistics of that, but again, I appreciate your appearance, and your very thoughtful responses to all of our questions, and with that, our hearing is adjourned.

[Whereupon, at 2:00 p.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Sally Katzen, Adjunct Professor and Public Interest/Public Service Fellow, University of Michigan Law School

Questions submitted by Chairman Brad Miller

Q1. The testimony Mr. Aitken, Acting Director of OIRA, offered in a House Judiciary Committee hearing repeatedly asserts that the new executive order amending E.O. 12866 simply memorializes current practice and, in particular, practices that began during your time at OMB. Do you wish to comment on the assertion that there is no meaningful change in policy represented by the provisions in E.O. 13422 relating to how regulatory proposals shall be prepared.

A1. If there were no meaningful change in policy represented by the provisions of Executive Order 13422, then why did the Administration invoke the prestige of the President and the authority of an executive order to achieve nothing? This President has not issued many executive orders and it seems to be inconsistent with his management style to use an executive order for a non-event. Finally, the changes in Executive Order 13422 do not reflect policies or practices of the Clinton Administration. Specifically, the Clinton Administration did not elevate market failures to a priority status for justifying rule-making; it did not require aggregation of projected costs and benefits at the pre-notice stage of rule-making; it did not require that regulatory policy officers be presidential appointees; it did not encourage the use of formal rule-making for resolution of issues; and it did not use OMB review for guidance documents which, by definition, do not have the force and effect of law.

Q2. Do you have any other points you wish to make for the record regarding E.O. 13422 and its likely application by the Bush Administration?

A2. Not at this time, thank you.

Questions submitted by Representative F. James Sensenbrenner, Jr.

Q1. Did President Clinton's E.O. 12866 require agencies to conduct Cost-Benefit Analyses for proposed regulations? If so, what harm would come from simply requiring them to report the aggregate of the analyses they already conducted? Is this such a big step?

A1. President Clinton's Executive Order required agencies to conduct cost/benefit analyses, to the maximum extent feasible, when they were proposing or issuing final rules. Executive Order 13422 requires agencies to aggregate costs and benefits of items listed in the Regulatory Agenda, which includes many items at the pre-notice of proposed rule-making stage, when the agency has made no decisions as to the course it is likely to pursue.

Q2. A major criticism of the Market Failure criterion is that some believe it elevates economic concerns above those of public health and safety, and that this contradicts Congressional guidance. Is this true? If so, why don't the following sections give agencies an "out" when they are presented with conflicting values?

Sec. 1, end of last sentence: "unless a statute requires another regulatory approach."

Sec. 1(b), end of last sentence: "to the extent permitted by law and where applicable."

A2. President Clinton's Executive Order included several references to the superiority of applicable law to provisions of an executive order; those references were not changed by the provisions of Executive Order 13422, nor could they be given that wherever there is a conflict, duly enacted law would trump a provision in an executive order. The agencies therefore have "an 'out'" where there is a direct conflict. The problem that many foresee, however, is that the amendment elevating economic concerns increases the burden on the agencies to either demonstrate that the law reflects congressional intent with respect to the particular issue they are addressing or to justify its proposal on economic as opposed to other, possibly more important or pertinent grounds.

Q3. One of the reasons agencies have increasingly turned to guidance documents in order to regulate industry is that they do not require public notice, public comment, or OMB notice. This has allowed for more flexible and reactive policies, but has sacrificed transparency, organization, and accountability. Do you believe

the recent OMB bulletin proposes a reasonable method of balancing these competing principles?

A3. The recent OMB bulletin is a good faith attempt to balance these and other competing principles. The problem, however, is that in some instances and for some agencies, the requirements of the bulletin will have the effect of reducing (possibly greatly reducing) the issuance of guidance, which tells both the agency staff and the regulated entities what is expected of them under existing regulations. Such guidance has the salutary effect of providing clarity to regulated entities and protecting them from haphazard enforcement of existing regulations by agency staff. In other words, there are and will be costs associated with the new bulletin.

Q4. In reference to the Good Guidance Bulletin, *you state in your testimony (page 9) that, "While each step can be justified as helping to produce better regulatory decisions, the cumulative effect is overwhelming." If you believe that the Bulletin is "justified as helping to produce better regulatory decisions," are your objections to the* Bulletin *related to policy or your view that OIRA has an insufficient budget?*

A4. The antecedent for "each step can be justified as helping to produce better regulatory decisions. . ." is the various bulletins, circulars, and guidance issued by the Bush Administration over the last several years, discussed at pages 6–9 of my written testimony. Each step (as in, each bulletin, circular or guidance), standing alone, can (as in, one can reasonably argue) be justified. "[T]he cumulative effect is overwhelming" refers to the agencies, not OIRA, and the fact that agency budgets have not kept up with the increasing demands made on the agencies by OIRA.

ANSWERS TO POST-HEARING QUESTIONS

Responses by David C. Vladeck, Director, Institute for Public Representation; Associate Professor of Law, Georgetown University Law Center

Questions submitted by Chairman Brad Miller

Q1. I am concerned about the implications for the public's right to know embedded in the changes to the Regulatory Policy Officers. As Presidential appointees with the power to "pre-approve" even starting a regulatory or guidance initiative, what might this mean for the ability of the public and public interest groups to know what has happened on issues dispensed with by these officers? Might this be an indirect way of by-passing some of the much-vaunted transparency that has so far marked the OMB E.O. 12866 process?

A1. This question was raised briefly during the hearing, and my answer then, as it is now, is that the structure of the new Executive Order invites the circumvention of the transparency provisions of the Executive Order 12866. As the Committee understands, Executive Order 12866, § 6(b), requires OMB to place on the record its exchanges with an agency during the course of a rule-making proceeding. It also requires OMB to put on the public record meetings between OMB and non-governmental parties relating to rule-makings. To be sure, the openness requirements of the Executive Order apply only during the rule-making process, and do not cover interactions between OMB and agencies, or OMB and outsiders, prior to the agency's development of a notice of proposed rule-making. But once the rule-making process begins, the Executive Order does require a fair degree of transparency.

Executive Order 13422 undermines the openness guarantee of Executive Order 12866 in two important ways. First, OMB review of guidance documents is *not* subject to any of the transparency requirements of section 6 of Executive Order 12866, which applies only to "regulatory actions" for "new and existing regulations." The drafters of Executive Order 13422 understood this limitation, but made no effort to expand the scope of section 6 to cover OMB review of guidance documents. This omission was not inadvertent. Instead, the omission was intended to permit OMB and agencies to develop guidance documents—and to integrate the input of regulated industry—behind closed doors, with no public record at all. Given OMB's history of serving as a conduit for industry, which of course led to the Graham memorandum and the addition of section 6(b) to the Executive Order, Congress ought to be wary of OMB's deliberate effort to exercise control over the issue of guidance documents insulated from any transparency or openness requirement.

Second, Executive Order 13422 promotes secrecy because it ensures that the pre-rule-making interchanges between OMB and the Policy Review Officers at the agencies will be off-the-record. The law is clear that dealings between OMB and agency officials that precede the commencement of rule-making are not subject to mandatory disclosure under the *Freedom of Information Act* ("FOIA"). Courts have ruled that these exchanges are "predecisional" and "deliberative" in character and thus may be shielded from disclosure under Exemption 5 to FOIA. *See Wolfe v. HHS,* 839 F.2d 768 (D.C. Cir. 1988) (en banc). As a result, even under Executive Order 12866 pre-rule-making consultations between OMB and agencies were not subject to disclosure. But Executive Order 13422 makes a bad situation worse. Under Executive Order 12866, the Regulatory Policy Officers were agency officials selected by the agency head, and these Officers owed their loyalty to the agency, not the White House. Thus, if OMB sought to force an agency to act in a way that was out of step with the desires of the agency head, the agency had tools to object, and to do so on the public record.

Executive Order 13422 reverses that presumption and puts a White House agent in charge of the agency's regulatory apparatus, which now extends not just to the agency's regulatory output, but also to non-binding agency guidance. Thus, the ability of the agency to resist OMB and follow the course the agency thinks best is diminished, if not destroyed. After all, the White House will now have its own appointee serving as the gatekeeper of the *agency*'s machinery. And, to make matters worse, all of these exchanges will take place off-the-record.

For these reasons, the answer to Chairman Miller's question—can OMB kill off a regulatory or guidance initiative an agency wants to take, and do so in a way that will escape public oversight?—is plainly "yes" under Executive Order 13422. And make no mistake, this is not an unintentional consequence of inattentive drafting. This is precisely the power that OMB has long coveted.

Q2. The new E.O. elevates market failure as the preferred standard for an agency to meet in explaining the rationale for a regulatory or guidance document. If you

have insights into how the President's proposed director of OIRA, Susan Dudley, might apply this standard, please share that with the Subcommittee.

A2. There is no need to speculate about how Ms. Dudley would apply the new "market failure" standard in the Executive Order were she to serve as the director or acting director of OIRA. Ms. Dudley has an extensive track record on this issue, which I urge the Subcommittee to review.[1] In summary, Ms. Dudley's writings suggest that she believes that markets almost never fail, and that government intervention is rarely if ever appropriate. Just consider one example. Ms. Dudley was virtually alone in opposing the advanced air bag rule-making just conducted by the National Highway Traffic Safety Administration. She did so on the ground that government intervention was not needed, notwithstanding the deaths of and injuries to children and women of short stature caused by first-generation air bags, because there was no evidence of market failure. Ms. Dudley was willing to disregard the deaths and injuries because she was confident—despite years of contrary evidence—that, if left alone, the market would provide a range of safety options to consumers and we ought to trust the market to give consumers adequate protection.[2]

Ms. Dudley's blind faith in the markets, and her hostility to government regulation, would make her an odd choice to head OIRA. If Ms. Dudley saw no market failure with regard to one-size-fits-all air bags, would she have let the Environmental Protection Agency phase lead out of gasoline, the Food and Drug Administration require that iron pills, the leading cause of poisonings in the United States, be sold in child-proof containers, or the Consumer Product Safety Commission outlaw the use of flammable material in children's sleep-wear? The point of regulation is to prevent market failure, not to pick up the pieces once the damage is done.

Q3. Do you have any other points you wish to make for the record regarding E.O. 13422?

A3. I think that my written statement to the Subcommittee covered the important points I want to make about the new Executive Order.

Questions submitted by Representative F. James Sensenbrenner, Jr.

Q1. Did President Clinton's E.O. 12866 require agencies to conduct cost-benefit analyses for proposed regulations? If so, what harm would come from simply requiring them to report the aggregate of the analyses they already conducted? Is this really a such a big step?

A1. With all respect, I do think that this is a big step. Let me explain why. To begin with, the requirement that agencies prepare cost-benefit analyses for proposed regulations was not an invention of President Clinton, but President Reagan, who institutionalized this requirement in Executive Order 12291. President Clinton's Order in fact modified that requirement in a way that is significant in answering your question; namely, it permitted, almost encouraged, agencies to cite non-quantifiable costs and benefits of regulation in their analyses. As I have previously discussed, agencies generally can calculate the likely costs of proposed regulation in terms of dollars and cents. But benefits are often far more difficult to quantify, and many benefits simply cannot be quantified. For instance, how does one assign a dollar value to each I.Q. point a child might lose as a result of lead exposure; to each day a family will have to endure a loved one on kidney dialysis, caused by the person's exposure to cadmium in the workplace; or damage to a wildlife preserve? Regulation also avoids unwarranted distributional impacts, protects vulnerable sub-populations (children, the elderly, the poor, for example), averts aesthetic harms, and seeks to advance social justice. None of these benefits can be quantified, let alone monetized in the manner the Executive Order contemplates.

To account for these difficulties, the Clinton Executive Order encourages agencies to monetize those benefits that it can monetize, but it "recogniz[ed] that some costs and benefits are difficult to quantify" and therefore told agencies that they should provide a "reasoned determination that the benefits of the intended regulation justify its costs." Executive Order 121866, § 1(b)(6).

The problem with the regulatory accounting provision of Executive Order 13422, § 4(c)(1)(B), is that it wholly ignores this important lesson. By requiring that the agency report its "best estimate of the combined aggregate costs and benefits of all

[1] Ms. Dudley's writings have been extensively critiqued in a report by Public Citizen and OMB Watch entitled *The Cost is Too High: How Susan Dudley Threatens Public Health Protections* (Sept. 2006) (*http://citizen.org/publications/release.cfm?ID=7448&seeID=2565&catID=126*).

[2] Susan E. Dudley, *Regulatory Studies Program Comments: Advanced Air Bars 7* (Dec. 17, 1998) (*http://www.mercatus.org/publications/pubid.1180/pub_detail.asp*).

of its regulations planned for that calendar year," the new Executive Order puts aside all of the non-quantifiable benefits that flow from regulation and reduces the calculus to hard, cold dollars and nothing more. And make no mistake, this reporting requirement will be used by OMB and others to seek limits on agency regulation on purely economic grounds, notwithstanding the fact that regulatory benefits are often not reducible to dollars and cents.

Q2. A major criticism of the market failure criterion is that some believe that it elevates economic concerns above those of public health and safety, and that this contradicts Congressional guidance. Is this true? If so, why don't the following sections give agencies an "out" when they are presented with conflicting values?

Sec. 1, end of last sentence: "unless a statute requires another regulatory approach."

Sec. 1(b), end of the last sentence: "to the extent permitted by law and where applicable."

A2. The short answer to this question is yes, the market failure criterion in Executive Order 13422 does indeed "elevate[] economic concerns above those of safety and health" in a way that undermines Congress' judgment, and no, the provisions of Section I of the Order, cited in the question, do not give agencies an "out." Let me explain the basis for my answer.

To begin with, there can be no serious question that the new Executive Order makes "market failure" the pivotal consideration in regulation. Indeed, it is difficult to see how the drafters of the Order could have been clearer or more emphatic about this point. As you know, the language in the new Executive Order marks a profound departure from that in its predecessor: Section 1(b) of Executive Order 12866 required the agency to "identify the problem that it intends to address. . .as well as the significance of that problem." Executive Order 13422 deletes that language and says that "[e]ach agency *shall* identify in writing the specific market failure. . .or other specific problem that it intends to address. . .." That substitution plainly signals that, from now on, OMB will expect to see an economic analysis of market failure as a precondition to regulation. And the use of the word "shall," the language of command, only underscores the mandatory nature of the requirement. The only "out" will be a convincing economic argument from the agency that market failure is not at the root of the "other specific problem" the agency intends to address. The problem here is that this is an "out" in name only, because OMB, and not the agency, makes the final decision as to whether the agency has made a sufficient case for regulation.

Moreover, it is hard to see how health and safety agencies will be able to point to "other specific problem[s]" unrelated to market failure when they seek to impose regulation. Let's not mince words: when we speak of health and safety regulation, "market failure" is a euphemistic way of saying that people have been killed or injured because of dangerous products, exposure to toxic chemicals, or some other hazard. The point of health and safety regulation is to prevent these deaths and injuries, not wait until they occur. Suppose an agency wants to impose regulation on food producers to reduce the risk of an emerging food-borne illness. Tens of thousands of consumers are made ill by food-borne contamination each year, but it is rare that a consumer can link his or her illness to the consumption of a single food product. Market forces thus place only a weak constraint on market behavior of food producers. But with regard to an emerging hazard, there is, by definition, no evidence of "market failure" because the needed evidence has not yet developed. How is that agency going to do business with OMB? The agency cannot pretend that it is seeking to address some "other specific problem." Nor would OMB permit it to, do so. The point here, of course, is that a regulatory system that properly functions seeks to avoid market failure, yet the new Executive Order appears to require agencies to wait until they can prove market failure—by pointing to needless deaths and injuries—before moving ahead with regulation.

Nor do the fragments of two provisions of Section 1 of Executive Order 13422 cited in the question give the agencies an "out," as the question suggests. Both provisions go to the *substance* of agency regulations, which must be governed by statute where there is an inconsistency between the statute and the Executive Order. Neither provision addresses the justification an agency must provide to OMB in order to *proceed* with a rule-making, which is the point of the "market failure" super-mandate imposed by Executive Order 13422. A review of the two provisions cited in the question drives this point home.

The question's first reference is to the last sentence of Section 1(a), which is quoted only in part. In full, the sentence reads: "Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maxi-

mize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributional impacts; and equity), unless a statute requires another approach."

Contrary to the implication in the question, this provision has no bearing on the justification the agency must provide to OMB to receive OMB clearance to publish a proposed or final rule. The provision addresses an altogether different question: If permitted to regulate, what regulatory approaches may the agency pursue? But nothing in this language relieves an agency of its obligation under the Executive Order to satisfy OMB that it may regulate in the first instance. One illustration should suffice. The Supreme Court has ruled that in promulgating standards to protect workers from exposure to toxic substances, the Occupational Safety and Health Administration ("OSHA") must regulate to the limits of technological and economic feasibility. *American Textile Manufacturers Assn v. Donovan,* 452 U.S. 490 (1981). That standard is arguably at odds with the "net benefits" standard articulated in Section I of the Executive Order. In such a case, OSHA would be free to follow its statutory mandate, not that imposed by the Executive Order. But OSHA would nonetheless be bound to justify to OMB its decision to proceed with regulation, and under the new Executive Order, would not be able to avoid defending its decision to act on the basis of market failure. There would be no other bases on which to justify regulation, and thus this fragment of Section 1 does not provide agencies an "out," as the question suggests.

Nor does the language at the end of Section 1(b) provide agencies an out. That language reiterates the concern set forth in the final sentence of Section 1(b), by providing that: "To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, *to the extent permitted by law and where applicable."* Once again, this language is a directive, mandated by settled law, that an Executive Order cannot trump a statute. For that reason, the Executive Order does not purport to, and could not, direct an agency to ignore statutory directives when issuing a regulation. But nothing in this language, or any other language in the Executive Order, relieves the agency's obligation under the Executive Order to explain to OMB on the basis of market failure why the agency is choosing to proceed with regulation.

Q3. One of the reasons agencies have increasingly turned to guidance documents in order to regulate industry is that they do not require public notice, public comment, or OMB notice. This has allowed for more flexible and reactive policies, but has sacrificed transparency, organization, and accountability. Do you believe the recent OMB bulletin proposes a reasonable method of balancing these competing principles?

A3. Before addressing the OMB Bulletin on guidance documents, it is necessary to emphasize that I do not agree with several of the explicit premises of the question. First, I do not know whether it is true, as the question suggests, that "agencies have increasingly turned to guidance documents." Having practiced administrative law for thirty years, I think that agencies have always used guidance documents, and have done so precisely because they can be issued quickly and flexibly, as needs arise. Second, I do not believe that agencies use guidance documents to avoid transparency and accountability. Unlike enforcement policies, which are often kept from public view, the entire point of guidance documents is to inform the public of the agency's views, and agencies are held accountable for the guidance they give. Woe to an agency that brings an enforcement action and seeks to distance itself from guidance the agency gave; the agency does so only at its peril. Third, I disagree with the question's suggestion that agencies have "turned to guidance documents in order to regulate industry." Guidance documents do not have the force of law; they do not "regulate" in any meaningful sense of the word.

Having said all of this, I do believe that, at times, agencies issue guidance documents instead of embarking on notice and comment rule-making, not to avoid giving OMB notice, but because OMB review has made the notice and comment rule-making process too time-consuming, too cumbersome, and too expensive to justify the commitment of agency resources to the issuance of a rule. Nothing in the new Executive Order responds to these concerns.

As to OMB's recent bulletin on guidance documents; I think that, because it is designed to carry forward the mandates of the new Executive Order, it is deeply flawed—for the reasons outlined in my testimony. Formalizing and making uniform the process by which agencies give advice is a tremendous mistake and will hamstring the ability of agencies to provide advice to regulated parties and the public at large. Because the Executive Order the bulletin seeks to implement is flawed, so too is the bulletin.

ANSWERS TO POST-HEARING QUESTIONS

Responses by William L. Kovacs, Vice President, Environment, Technology, and Regulatory Affairs, U.S. Chamber of Commerce

Questions submitted by Representative F. James Sensenbrenner, Jr.

Q1. Did President Clinton's E.O. 12866 require agencies to conduct cost-benefit analyses for proposed regulations? If so, what harm would come from simply requiring them to report the aggregate of the analyses they already conducted? Is this really such a big step?

A1. Yes, President Clinton's E.O. 12866 already requires agencies to conduct cost-benefit analyses for proposed regulations that will have a significant impact on the economy. E.O. 12866 requires every federal agency to determine whether a regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the analytical requirements of the executive order. A "significant" regulatory action is defined as one that is likely to result in an annual impact on the economy of $100 million or more.

Since federal agencies are already required to conduct a cost-benefit analysis for each proposed significant new regulation, it is not a big step for them to simply add up the aggregate cost impact of all new regulations for a given year. As I stated in my original written testimony, **rules do not operate in a vacuum.** For an accurate assessment of a rule's actual cost impact, it *must* be considered in conjunction with other rules. In the interest of transparency and full disclosure, the public should be made aware of the aggregate costs associated with an agency's annual rule-makings.

Q2. A major criticism of the market failure criterion is that some believe it elevates economic concerns above those of public health and safety, and that this contradicts Congressional guidance. Is this true? If so, why don't the following sections give agencies an "out" when they are presented with conflicting values?

a. Section 1, end of last sentence: "unless a statute requires another regulatory approach," or

b. Section 1(b), end of last sentence: "to the extent permitted by law and where applicable."

A2. Ironically, the "market failure" criterion, which has been so derided by critics of the new executive order, was first detailed in the Clinton Administration's 1996 guidelines for economic analysis under Executive Order 12866.[1] Those guidelines specifically noted that market failures, externalities, natural monopolies, market power, and asymmetric information are all essential components of any economic analysis. As a result, it was the Clinton Administration that emphasized the importance of economic analysis in rule-making.

What President Bush's executive order did was actually broaden the scope of the Clinton guidelines to allow for an agency to state additional justifications for a rule-making. In that way, the market failure criterion would not be elevated above public health and safety concerns. In 2003, the Bush Administration clearly delineated the additional justifications beyond market failure—which included the protection of civil rights, privacy, personal freedom, and other concerns.[2] More importantly—as Rep. Sensenbrenner notes in his question—the last phrase in Section 1 and 1(b) of the executive order clearly provide agencies with choices when they are presented with conflicting values.

It is only logical that federal agencies should be required to identify a problem that justifies a regulation before proceeding with a rule-making—whether that problem is a market failure or something else. In this way, we can be assured that a comprehensive and thorough analysis of all potential impacts of a rule-making has been conducted.

Q3. One of the reasons agencies have increasing turned to guidance documents in order to regulate industry is that they do not require public notice, public comment, or OMB notice. This has allowed for more flexible and reactive policies, but has sacrificed transparency, organization, and accountability. Do you believe the recent OMB bulletin proposes a reasonable method of balancing these competing principles?

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[1] OMB, "Economic Analysis of Federal Regulations Under Executive Order 12866" (Jan. 11, 1996).

[2] See OMB Circular A–4, at p. 4–6.

A3. Yes. The OMB *Bulletin on Good Guidance Practices* (GGP) does not prohibit agencies from issuing guidance documents. Agencies can, and should, continue to utilize guidance documents to provide the public with information on how to comply with a particular rule or regulation. Rather, the GGP establishes uniform policies and procedures for the development, issuance and use of significant guidance documents.

The purpose of the GGP is to ensure that guidance documents of Executive Branch departments and agencies are developed with appropriate review and public participation. It requires that guidance documents be accessible and transparent to the public, and not improperly treated as legally binding. GGP does this by requiring that each guidance document contain certain standard elements, such as identifying the document as guidance, the name of the issuing office, the activity and persons to whom it applies, the date of issuance, and the title and docket number. Surely such requirements, which will vastly improve transparency and accountability in an agency's regulatory activities, are not overly oppressive.

Perhaps the most important new GGP requirement, however, is that agencies avoid "mandatory" language in guidance documents. By law, guidance documents are advisory only; that is, they do not have legally binding effect. Yet they have practical binding effect when the agencies use them to establish criteria that affect the rights and obligations of private persons. By eliminating mandatory language—words such as "must" and "shall"—the growing problem of "regulation by guidance document" will finally be addressed.

The GGP also establishes public access and feedback procedure. Agencies are required to maintain a current list of significant guidance documents on their web sites and to provide a means for the public to electronically submit comments. The Chamber supports, and has always supported, efforts to improve the operation of government by improving the opportunity for the public to participate in the policy-making process. Such participation allows the public to have a voice in the making of the laws that regulate them, and protects them from arbitrary decisions by federal agencies.

Q4. Does E.O. 13422 (or the Good Guidance Bulletin *for that matter require any new analysis to be conducted, or does it simply require agencies to report the work they have already done? Do you believe that reporting this work could lead to "paralysis by analysis?"*

A4. President Bush's E.O. 13422 does not require any new analysis by an agency. What it does require is for an agency to have a reason for creating a new regulation. It simply asks an agency to state the reason for the rule, and estimate how much it will cost, particularly in connection with other rules issued that year by the agency. Presumably, these are things the agency can readily supply, and therefore are *not* new and onerous requirements.

Moreover, the argument that E.O. 13422 (and GGP) will lead to "paralysis by analysis" is specious. Similar arguments were made regarding the *Data Quality Act* (DQA)—namely, critics argued that it would "shut down" the regulatory process by forcing agencies to respond to public claims of disseminating faulty information. In reality, very few DQA petitions were filed with federal agencies. For example, in FY 2006, only 22 DQA petitions were filed with government agencies, and only six appeals.

Clearly, the critics were wrong about the DQA, and they are almost certainly wrong about E.O. 13422. The President's actions will serve to bring transparency and accountability to an opaque and complex process. This effort should be lauded.

Q5. OMB has stated that they don't know exactly who currently holds the position of Regulatory Policy Officer at every agency. Do you think the decision to have those duties executed by a Presidential Appointee is a responsible way to better organize this process and bring about more transparency and accountability?

A5. The fact that OMB—which is responsible for overseeing the management of the executive branch agencies—cannot identify an agency's regulatory policy person speaks volumes regarding the current state of the regulatory process.

By appointing a Regulatory Policy Officer, the President effectively creates a single point-of-contact for all regulatory issues within an agency. This appointment will bring organization, transparency, and accountability to policy-making in general, and it will further improve the President's ability to manage the executive agencies in his Administration. The Regulatory Policy Officer also brings accountability to the agency by ensuring that the President's executive order is implemented.

Questions submitted by Representative Brian Baird

Q1. "From what you have just said, the Chamber of Commerce is very interested in transparency. Was it the Chamber's official position back then, and is it now, that the Vice President of the United States should share information about who consulted with him on energy policy? . . .For the record, then, I would just request that you would report back to this committee on. . .to please send us a letter, which we will convey to the Vice President, asking him, on behalf of the Chamber of Commerce, to share the names of the people who helped draft his energy policy."—Hearing transcript, page 49–50.

A1. Because Rep. Baird's question is about transparency in government, let me first directly state the Chamber's current and historical position on this issue, and then I will apply the Chamber policy to Rep. Baird's question.

(1) Chamber Policy

The Chamber's long held position was proposed, voted on and approved by our Board of Directors, and codified into official policy:

> *A free flow of information from and concerning all branches of government at all levels is a right of the public and is essential to our democratic society. . .. It is the responsibility of government to protect and preserve this constitutional guarantee by a policy of full disclosure of information. Except for matters clearly affecting national security or otherwise covered by statute, all business of government should be fully disclosed to the public. The burden of proof must rest with government in every instance to justify withholding any information from the public.*
>
> *Policy Declarations, U.S. Chamber of Commerce*

As our policy declaration makes clear, the Chamber is one of the strongest proponents of an open and accessible Federal Government. This is evidenced not just in our policy statements, but also in our public activities. Consider, for example, our continuing support of the Administration's Electronic Government, or "E-Gov," Initiative, which is an effort to make information more accessible to the public through advanced technology and the Internet. Or consider the Chamber's unfettered support for government "sunshine" laws, improved *Freedom of Information Act* legislation, the federal financial grants and contracts online database, *Data Access and the Data Quality Act* —all of which promote transparency in government operations.

Similarly, the Chamber has always supported an open regulatory system that would allow the public access to, and a voice in, the federal rule-making process. That is why the Chamber testified at the February 13, 2007, hearing in support of Executive Order 13422, and the *Final Bulletin on Agency Good Guidance Practices*—because these documents broaden public input into and increase responsible management of the current regulatory system.

The purpose of the Subcommittee hearing was ostensibly to discuss the scope and impact of the Administration's Executive Order 13422, which modifies Executive Order 12866, and specifically whether it constitutes an impermissible expansion of executive authority over federal agencies. As stated in my oral testimony, E.O. 13422 is not only permissible, but also a necessary tool for the President to manage his agencies and the regulatory process.

Executive Order 13422 was issued by President Bush for two reasons. First, it was intended to prevent federal agencies from circumventing the rule-making process by using guidance documents to regulate the public. Guidance documents do not have to undergo the same rigorous analytical requirements of the rule-making process as proposed regulations, so agencies tend to couch regulatory language in guidance documents as a way to compel public compliance. Executive Order 13422 corrects that abuse by including guidance documents within the scope of the analytical requirements of Executive Order 12866. Second, and perhaps more importantly, it is an attempt by the President to manage his executive agencies. It does this in three ways: (1) by ensuring agencies state why a rule is needed, (2) by ensuring agencies give an accurate accounting of costs and benefits of an individual rule and the aggregate costs and benefits of all rules issued by the agency that year, and (3) by creating a Regulatory Policy Officer (RPO) within each agency to ensure that the executive order is implemented by the agency. The RPO is a political appointee, responsible to the President, who must coordinate with OMB.

In their testimony before the subcommittee, each of the other three witnesses[3] decried the creation of the RPO, claiming that it "politicized" the regulatory process by allowing a political appointee—who reports to the President and not Congress—control over an agency's regulatory output. Because of this fact, the other witnesses believed that the activities of the RPO are intended to be opaque and shielded from public scrutiny. In other words, they feared that the activities of the RPO will not be subject to the same transparency and accountability as, say, an agency administrator, who is confirmed by, and reports to, Congress.

When asked directly about the accountability and transparency of the RPO by the Members of the Subcommittee, I stated that, first and foremost, the RPO was most certainly going to be held accountable—to the Chief Executive. Much like the agency administrator, the RPO serves at the pleasure of the President and is ultimately responsible to him. Second, I stated that the Chamber favored extending transparency, not just to regulations, guidance documents, and the RPO, but also to the entire regulatory process. That is, the Chamber would like to see all the reports, studies, white papers, third-party analyses, documents, and data that form the underlying basis of an agency's regulatory decision-making to be made available for public scrutiny and subject to open peer review. No other witness took such a position on transparency.

It is only through an open peer review of such underlying technical documents and analyses that we can ensure that:

- The public remains fully informed of the rules that regulate them;
- Documents forming the basis of a rule will be improved through critical review;
- Final regulations will be narrowly tailored to address a specific harm; and
- The public will have had the opportunity to participate at every step in the process.

(2) Application of the Chamber's Policy to Rep. Baird's Question

Following my statement of "total transparency," Representative Baird suggested that the Chamber's support of transparency was actually "selective." That is, the Chamber claims to want transparency in government, but, in fact, doesn't want it extended to the activities of the Executive Office. By way of example, Representative Baird cited the controversy surrounding Vice President Cheney's National Energy Policy Development Group (NEPDG), and whether the identification of the participants and substance of the preliminary meetings should be made publicly available. "If [transparency] is what you believe, apply it equitably across the Executive Branch," Representative Baird stated at the hearing.

Transparency is what the Chamber espouses, and favors its application across all three branches of government. Yet, as even Representative Baird must agree, the doctrine of open government must take a back seat to national security concerns, the laws enacted by Congress, and the U.S. Constitution. That is why official Chamber policy specifically states that we favor full disclosure of information in all matters of government *except for matters clearly affecting national security or otherwise covered by statute.* In other words, if there are, for example, national security reasons (terrorist threats), constitutional reasons (separation of powers), or legal reasons (statutes or court decisions) for restricting transparency, then these reasons must be respected.

In the case of Vice President Cheney's energy task force, the question of whether the identification of the participants and substance of the preliminary meetings should be made public is governed both by separation of power concerns, and more directly, by statute—namely the *Federal Advisory Committee Act* (FACA).[4] Under FACA, the work of executive advisory groups that include non-federal employees must be publicly disclosed. Yet the Administration has affirmatively stated that NEPDG was composed of all federal employees, and therefore exempt from FACA. If, in fact, any non-governmental employees subsequently are determined to have been present at some of the NEPDG meetings, this would not mean that the FACA exemption is lost. The non-governmental employees would still have to be deemed *de facto* members of the advisory group in order for disclosure to occur, as was the case with the health care task force headed by former First Lady Hillary Rodham

[3] Sally Katzen, David C. Vladeck, and Rick Melberth. Witnesses' written testimony is accessible at: *http://science.house.gov/publications/hearings_markups_detai1s.aspx?NewsID=1269*

[4] 5 U.S.C.S. Appendix Sec. 1, et seq.

Clinton.[5] If the courts ultimately determine that this was also the case with the NEPDG, then the law would require public disclosure.

The Chamber's policy will continue to reflect a respect for the laws of this nation—as passed by Congress—including FACA. If the language, application, or impact of a particular law is not to the liking of Congress, then it is certainly within the power of Congress to change that law. Until then, our policy will remain unchanged.

Conclusion

I hope this helps to clarify the Chamber's position on both E.O. 13422, and transparency in government. As I have tried to make clear, the Chamber strongly supports the President's effort to manage the regulatory process, and further advocates opening the entire regulatory process to public scrutiny—from the underlying documents and discussions that form the basis of regulations, to the final regulations themselves. It is only through complete transparency and open peer review that we can ensure that regulations and guidance documents are sound, balanced, cost-effective, and ultimately fair.

The Chamber is grateful for the opportunity to present its views about this important topic.

[5] *Association of American Physicians v. Clinton,* 302 U.S. App. D.C. 208, 997 F.2d 898 (CADC 1993). Court held that, although non-government employees had not been officially named to the committee, they had become so involved in the task force's activities that they were "functionally indistinguishable" from the designated members.

ANSWERS TO POST-HEARING QUESTIONS

Responses by Rick Melberth, Director of Regulatory Policy, OMB Watch

Questions submitted by Chairman Brad Miller

Q1. I am concerned about the implications for the public's right to know embedded in the changes to the Regulatory Policy Officers. As Presidential appointees with the power to "pre-approve" even starting a regulatory or guidance initiative, what might this mean for the ability of the public and public interest groups to know what has happened on issues dispensed with by these officers? Might this be an indirect way of by-passing some of the much-vaunted transparency that has so far marked the OMB E.O. 12866 process?

A1. The public's right to know what happens to regulatory issues is already severely limited in the pre-rule-making process under E.O. 12866. OIRA's involvement as the gatekeeper in the process means that agencies' submissions to OIRA—the first public notice of agencies' proposed actions—are already substantially impacted by OIRA's pre-rule-making negotiations as a 2003 GAO report described.[1] Proposed regulations, however, are at least initiated in the agencies with the expertise to recognize that a problem may require regulatory action. The process can begin, data may be collected, analyses conducted, and some determination may be made of the problem to be addressed. Although OIRA's influence is substantial, the final political decisions within agencies about moving forward with regulations are made by the agency heads.

The installation of Presidential appointees at the agency level concentrates OIRA's authority at the expense of agency personnel. It shifts the decision to initiate regulations and guidance to someone less familiar with the scope of the problem and adds political considerations that should only occur at the highest levels of the agencies. These appointees can stop regulations from ever being considered.

We believe the most damaging aspect of this political influence within agencies is that the *public will never know* what issues were dispensed with inside the agencies. The pre-rule-making stage becomes even more remote from the public. While we strongly disagree with this change in the Regulatory Policy Officer's responsibility, if it is implemented, then the larger question is the near total lack of transparency and disclosure during the pre-rule-making stage. The public can never know what alternatives were dismissed or what remedies were forced onto agencies by political calculations. This process is highly undemocratic and secretive.

Q2. The new E.O. elevates market failure as the preferred standard for an agency to meet in explaining the rationale for a regulatory or guidance document. If you have an insight into how the President's proposed director of OIRA, Susan Dudley, might apply this standard, please share that with the Subcommittee.

A2. In September 2006, after President Bush nominated her to be OIRA administrator, OMB Watch and Public Citizen issued an analysis of Susan Dudley's writings and comments.[2] In that report we conclude:

> Dudley believes that an agency must do more than prove that a regulation's benefits outweigh its costs. Dudley has stated that "[e]ven policies supported by the best benefit-cost analysis are not likely to be socially optimal substitutes for market forces unless they correct a market failure." With her skepticism about whether regulation can serve any goal other than correcting a market failure (which, as she has defined it, would be an impossibility), Dudley would bog the agencies down in endless analysis, stalling regulations and leaving the public at risk.

We believe there are three reasons why Dudley would be a threat to public protections if she were the administrator of OIRA. First, she has an ideological opposition to regulations which leads her to use policy tools in biased ways. In her writings she shifts and sometimes uses contradictory reasoning to conclude that regulations are not justified. From her record, one can only conclude that she would demand impossible requirements agencies could not meet.

Second, the elevation of additional economic analyses such as market failure, senior death discounts, and a free-market-first approach under Dudley's direction could

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[1] General Accounting Office, *RULE-MAKING: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews,* September 2003. Available at *www.gao.gov/cgi-bin/getrpt?GAO-03-929*.

[2] The full report, *The Cost Is Too High: How Susan Dudley Threatens Public Protections,* can be read online or downloaded at *http://www.ombwatch.org/regs/2006/dudleyreport.pdf*.

result in substituting these economic considerations for non-economic ones. Even in policy areas where other considerations are mandated as primary considerations, such as regulations promulgated by OSHA in which costs are not placed above worker safety, we believe Dudley's reliance on economics would be determinative.

Dudley also is a strong advocate for regulatory sunsets which would severely weaken public protections. She supports the position that agencies should justify a second, and third, and fourth time the need for critical regulations as they expire under sunset provisions. Given how ossified the regulatory process already is, this position leads to a de facto roll back of regulations already implemented.

Third, we oppose her nomination because of her very close ties to corporate interests which have worked strenuously to delay, diminish and defeat health, safety, environmental and civil rights protections. The regulatory process is already heavily tilted toward special interests. We believe Dudley would further tilt the playing field toward the interests that have supported her work.

In light of this record, we believe Dudley would apply market failure analyses and other provisions of the amended E.O. to delay if not to stop public protections.

Q3. Do you have any other points you wish to make for the record regarding E.O. 13422?

A3. OMB Watch has just completed a final analysis[3] of the potential impacts of E.O. 13422 and OMB's *Final Bulletin for Agency Good Guidance Practices.* In its conclusion, we argue that these regulatory process changes further concentrate control in the White House, especially in OIRA, at the expense of both the separation of powers and agency discretion. OIRA will be able to further delay the issuance of regulations and guidance documents. These delays will have real impacts on people's lives. And submitting guidance documents to OIRA review will hurt regulated entities which rely on agency guidance to conduct daily activities.

E.O. 13422 and the good guidance bulletin move the regulatory process in the wrong direction and this will have real consequences for our nation's public safeguards. Our government should be doing more to protect the public, not less.

Questions submitted by Representative F. James Sensenbrenner, Jr.

Q1. Did President Clinton's E.O. 12866 require agencies to conduct cost-benefit analyses for proposed regulations? If so, what harm would come from simply requiring them to report the aggregate of the analyses they already conducted? Is this really such a big step?

A1. E.O. 12866 requires agencies to conduct cost-benefit analyses of proposed regulations. These are individual analyses conducted for a very wide range of types of regulations even for those within one specific agency like the Department of Agriculture or the Department of Labor. The harm that comes from aggregating costs and benefits from such diverse analyses is in how those aggregate numbers are used.

Congress requires OMB to report these aggregated cost and benefit totals in its annual *Report to Congress on the Costs and Benefits of Federal Regulations.* The 2007 Draft report just issued March 12th states: "OMB has chosen a ten-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today." But why use ten years? Why not five or fifteen? The logic regarding the questionable relevance of pre-regulation estimates is as valid for regulations conducted at any time. The aggregated numbers have little basis in reality.

U.S. businesses excel at adapting to changing business conditions; they adapt technologically, they adapt by learning from experience. Thus the pre-regulation cost estimates provided by businesses for use in cost-benefit analyses are hypothetical, and possibly biased. A more reasonable approach would be to perform *ex post* studies of costs and benefits (to the extent that either can be quantified). These *ex post* numbers are relatively useless in the aggregate.

The best arguments against aggregating costs and benefits are provided in OMB's first annual report in 1997, *Report to Congress on the Costs and Benefits of Federal Regulations.*[4]

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[3] OMB Watch, *A Failure to Govern: Bush's Attack on the Regulatory Process,* March 2007. Available at *http://www.ombwatch.org/regs/PDFs/FailuretoGovern.pdf*

[4] Office of Management and Budget, *Report to Congress on the Costs and Benefits of Federal Regulations.* September 30, 1997. Available at *http://www.whitehouse.gov/omb/inforeg/rcongress.html*

> Third, it is important to ask: What public policy purposes do aggregate estimates serve if the ultimate goal is to develop the information necessary to make decisions about specific regulatory programs or program elements? And, in particular: In what ways can these estimates help support the recommendations to reform the regulatory system required of the Director by Section 645 (a)(4)? Clearly, knowing the costs and benefits of individual proposals for regulatory actions and their alternatives, including the alternative of no action, enables policy officials to make decisions that improve society's well being. But for reasons discussed below, knowing the *total* costs and *total* benefits of all of the many and diverse regulations that the Federal Government has issued provides little specific guidance for decisions on reforming regulatory programs. [Chapter II, Overview]

The report goes on to argue that "it is extremely difficult, if not impossible, to estimate the actual total costs and benefits of all existing federal regulations with any degree of precision" because of two primary problems. First, is the problem of what baseline to use in order to make these aggregate numbers meaningful. "Could a civil society even exist without regulation? In other words, what do we use as the baseline for world without any regulation?"

OMB provides a number of problems with trying to identify a baseline for meaningful comparison. Problems include the *ex ante vs. ex post* issue raised above, the dynamic quality of the economy, and the dangers of attributing changing behavior to the presence of federal regulation as opposed to State and local regulation, tort claims, and/or public pressure. Businesses simply cannot accurately calculate the costs of compliance.

Second, in aggregating costs and benefits, one is comparing apples to oranges to "kiwis, grapefruit, etc." The cost-benefit analyses "vary in quality, methodology, and type of regulatory costs included." And not all regulations are the same. Environmental, social (public health, consumer and workplace protections, civil rights), economic, transfer payments, and process regulations require very different approaches.

OMB Watch believes that aggregating costs and benefit has no useful purpose to policy-makers because there is no connection to a problem government is trying to solve. Thus the only uses can be for creating a political straw man or for use in developing regulatory budgets which advance an already tenuous economic framework over the regulatory process. Regulatory budgets cap annual compliance costs of regulations, and as we've argued here, there is no reliable way of knowing the extent of these costs. Agencies must submit "combined aggregate costs and benefits of all its regulations planned for that calendar year *to assist with the identification of priorities."* [emphasis added] This language from E.O. 13422 provides further evidence that the intent is to use aggregated numbers for policy-making.

Q2. A major criticism of the market failure criterion is that some believe it elevates economic concerns above those of public health and safety, and that this contradicts Congressional guidance. Is this true? If so, why don't the following sections give agencies an out when they are presented with conflicting values?

Sec. 1, end of last sentence: "unless a statute requires another regulatory approach."

Sec. 1(b), end of sentence: "to the extent permitted by law and where applicable."

A2. We believe that economic concerns are already elevated above public health, workplace safety, environmental and civil rights concerns. Under the Bush Administration, these economic considerations have been advanced and politicized beyond the limits they had in previous administrations as we have documented for six years. The language quoted above from E.O. 12866 might be applicable in a regulatory implementation scheme in which OIRA acted as a counselor instead of a gatekeeper. These sections may provide a legal exit strategy when an agency is challenged. The practical effect, however, is that when one agency, OIRA, has the sole responsibility for overseeing an agency's proposed rules, has control over the agency's budget, and has the ability to keep an agency in an endless loop of regulatory analyses, OIRA will get nearly all of what it wants. This situation is exasperated by the lack of transparency in OIRA's role in the pre-rule-making process.

Q3. One of the reasons agencies have increasingly turned to guidance documents in order to regulate industry is that they do not require public notice, public comment, or OMB notice. This has allowed for more flexibility and reactive policies, but has sacrificed transparency, organization, and accountability. Do you believe the recent OMB bulletin proposes a reasonable method of balancing these competing principles?

A3. We would add to the list of reasons why agencies have turned to guidance documents the cumbersome and incredibly slow pace of getting regulations promulgated. Focusing on guidance documents ignores the real regulatory problems that exist in the process. The process is dysfunctional: it is too centralized, OIRA lacks the staff and expertise to judge the adequacy of the non-economic aspects of complex regulations, and it has increasingly imposed a once-size-fits-all approach to the analytical approaches used in the process.

Far from providing a reasonable method of balancing the principles cited above, submitting significant guidance documents to a review process similar to that for regulations sacrifices all of the principles mentioned. One more aspect of agency action is subject to OIRA's black box of regulatory review thus sacrificing transparency and accountability; adding more categories for the small staff at OIRA to review sacrifices agency flexibility and reactivity to anything more than an individual request. That results in providing guidance one transaction at a time.

Instead of implementing good guidance practices, OIRA would have served the administration and the public far better if it had attempted to fix the problems that drive agencies to issue guidance in the place of regulation.

Appendix 2:

Additional Material for the Record

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

April 25, 2007

M-07-13

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES, AND INDEPENDENT REGULATORY AGENCIES

FROM: Rob Portman

SUBJECT: Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices

On January 18, 2007, the President issued Executive Order (EO) 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review." On the same day, and in connection with EO 13422, I issued an Office of Management and Budget (OMB) Bulletin on Agency Good Guidance Practices (Bulletin).

The primary focus of EO 13422 and the Bulletin is on improving the way the Federal government does business with respect to guidance documents – by increasing their quality, transparency, accountability, and coordination. Guidance documents, used properly, can have important benefits. These include, for example, advising and assisting individuals, small businesses and other regulated entities in their compliance with agency regulations. When an agency issues a guidance document that has a significant impact on society, the guidance document should be subject to an appropriate level of review – by the public, within an agency, and by other Federal agencies.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) has primary responsibility for implementing EO 12866, as amended by EO 13422, and the Bulletin. To assist your agencies in implementing EO 13422 and Bulletin, OIRA has prepared the attached compliance assistance memorandum which describes what agencies should do to comply with the EO and the Bulletin. Please circulate this memorandum to the appropriate officials within your agency for immediate attention.

OMB looks forward to working with your agencies in the implementation of EO 12866, as amended, and the Bulletin.

Attachment

ADMINISTRATOR
OFFICE OF
INFORMATION AND
REGULATORY AFFAIRS

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

April 25, 2007

MEMORANDUM FOR REGULATORY POLICY OFFICERS

FROM: Susan E. Dudley SED
Administrator
Office of Information and Regulatory Affairs

SUBJECT: Implementation of the OMB Bulletin on Good Guidance Practices and Executive Order 13422 (amending Executive Order 12866)

On January 18, 2007, the President issued Executive Order (EO) 13422, "Amendment to Executive Order 12866 for Regulatory Planning and Review." On that same day, the OMB Director issued a related document, the OMB Bulletin on Agency Good Guidance Practices (the Bulletin). The primary focus of the Executive Order and the Bulletin is on improving the way the Federal government does business with respect to guidance documents – by increasing their quality, transparency, accountability, and coordination.

The Bulletin, which OMB issued after seeking public comment on a proposed version, establishes policies and procedures for agencies to apply in their development and issuance of "significant" and "economically significant" guidance documents. The Bulletin will ensure that guidance documents are of high quality, developed with appropriate agency review and public participation, and readily accessible by the public.

The principal change made by EO 13422 is that it amends EO 12866 to establish a process that will provide an opportunity for interagency coordination and review of significant guidance documents prior to their issuance. EO 13422 also amends EO 12866 in several other ways. To ensure appropriate accountability, the EO modifies the procedures for an agency's adoption of its annual Regulatory Plan and requires that an agency's Regulatory Policy Officer be a Presidential appointee. The EO also updates the Principles of Regulation in EO 12866 to reflect the guidance-coordination provisions that are added by EO 13422 as well as pre-existing OMB guidance. Finally, the EO invites agencies to consider whether they would want to rely on formal rulemaking procedures for resolving complex determinations.

Within OMB, the Office of Information and Regulatory Affairs (OIRA) has primary responsibility for implementing EO 12866, as amended, and the Bulletin. To assist agencies in their implementation of the EO and Bulletin, OIRA has prepared and is now issuing this memorandum that provides answers to a number of questions. Agencies should also consult the preamble to the Bulletin for additional implementation assistance.

If your agencies have any questions about the attached implementation assistance, or about the EO or the Bulletin, they may contact Margaret Malanoski at (202) 395-3122 or Margaret_A._Malanoski@omb.eop.gov.

OIRA looks forward to working with your agencies in implementing the EO and Bulletin.

Attachment

A. General Information

1. When do Executive Order 13422 and the Agency Good Guidance Practices Bulletin take effect?

Executive Order 13422 (Executive Order) became effective when it was signed by the President, on January 18, 2007.

The requirements of the Agency Good Guidance Practices Bulletin (Bulletin) will take effect on July 24, 2007. However, for significant guidance documents promulgated prior to January 25, 2007, agencies have until August 23, 2007 to comply with the requirements of Section III of the Bulletin. For documents promulgated after January 25, 2007, agencies should comply with the requirements of Section III of the Bulletin by July 24, 2007 or within thirty (30) days of issuance of the guidance document, whichever is later.

Agencies are encouraged to comply with the provisions of the Bulletin sooner if possible.

2. What agencies are covered by the Executive Order and the Bulletin?

The Executive Order and the Bulletin as a whole apply to all Federal agencies, except for the independent regulatory agencies as defined in 44 U.S.C. § 3502. (Sec. 3(b) of the Executive Order). The scope of agencies covered by the Bulletin and the Executive Order does not differ from the scope of agencies covered by Executive Order 12866.

The independent regulatory agencies are included in provisions concerning the "Unified Regulatory Agenda" (Sec. 4(b) of the Executive Order) and "The Regulatory Plan" (Sec. 4(c) of the Executive Order) and they must comply with the new requirements for the "Unified Regulatory Agenda" (Sec. 4(b) of the Executive Order) contained in the Executive Order. As OMB requested in 1993 following the issuance of Executive Order 12866, the independent agencies are requested on a voluntary basis to adhere to the provisions of the Executive Order that may be pertinent to their activities.

B. Guidance Questions -- Applicable to <u>Both the Bulletin and the Executive Order</u>

3. What types of guidance documents are covered by the Bulletin and by the Executive Order?

Both the Executive Order and the Bulletin define "guidance documents" as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue."

The definition is not limited to written guidance materials; it encompasses all guidance materials regardless of format, including guidance offered through video, audio tapes, interactive web-based software, or other innovative formats. Guidance documents may be currently referred to by a variety of names, such as interpretive memoranda, policy statements, guidances, manuals, circulars, memoranda, bulletins, or advisories.

4. What types of guidance documents are not covered by the Bulletin and by the Executive Order?

Guidance documents that are not significant are not covered by the Bulletin or the Executive Order. Further, Section I(4) of the Bulletin clarifies what is not a significant guidance document.

5. What is a "significant" guidance document?

Both the Bulletin (Sec. I(4)) and the Executive Order (Sec. 3(h)) define a "significant" guidance document as a guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:

(1) lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
(2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
(3) materially alter the budgetary impacts of entitlements, grants, user fees or loan programs or the rights or obligations of recipients thereof; or
(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

OIRA will work with agencies in applying the definition of "significant guidance" to the agency's guidance documents.

6. What is an "economically significant" guidance document and how is it related to a "significant" guidance document?

The Bulletin defines an "economically significant guidance document" as a "significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant documents do not include guidance documents on Federal expenditures and receipts." Therefore, economically significant guidance documents are a subset of significant guidance documents.

The Executive Order does not define "economically significant" guidance documents nor does it impose a separate process for "economically significant" guidance documents. Therefore, guidance documents that meet the definition of "economically significant" in

the Bulletin will be a "significant" guidance document for the purposes of the Executive Order.

If agency staff are uncertain about whether a guidance document should be classified as economically significant, they may contact OIRA for assistance.

7. Does either the Executive Order or the Bulletin require agencies to prepare a benefit-cost analysis for guidance documents as agencies are required to do for regulations?

No. The amendments to Executive Order 12866 did not alter the Section 6 requirements for analysis of regulations – specifically Sec. 6 (a)(3)(B)-(C) – to include guidance documents. The requirements for significant guidance documents (Sec. 9 of the Executive Order) do not impose similar analytical requirements.

In determining whether a guidance document is economically significant, agencies are not expected to complete a benefit-cost analysis or to do more than they currently do when they make preliminary recommendations to OIRA about the designation of regulations under Executive Order 12866. Rather, we expect agencies to use common-sense principles and readily available facts and assumptions in making their evaluation of whether a guidance document is reasonably likely to have an impact of $100 million or more annually. We recommend that the agency as part of its determination, consider both the expected adoption rate of guidance, in whole or in part, and the potential benefits that would occur with such adoption. If information to make reasonable assumptions is not available, we suggest that the agency consider the effect of the guidance as if it were adopted widely by all affected parties.

C. Guidance Questions -- Applicable to Requirements specific to the Bulletin

8. Under the Bulletin, what are the requirements for the content of "significant" guidance documents?

The Bulletin requires that significant guidance documents: (i) include the term "guidance" or its functional equivalent; (ii) identify the agenc(ies) or office(s) issuing the document; (iii) identify the activity to which and the persons to whom the document applies; (iv) include the date of issuance; (v) note if it is a revision to a previously issued guidance document and, if so, identify the guidance that it revises or replaces; (vi) provide the title of the guidance and any document identification number, if one exists; and (vii) include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets.

9. Under the Bulletin, what information are agencies required to post on their Web sites?

The Bulletin requires each agency to maintain a current electronic list of all significant guidance documents in effect on its Web site – or as a link on an agency's Web site to the electronic list posted on a component or subagency's Web site. The agency must provide a link from the current list to each significant guidance document that is in effect.

The agency list of significant guidance documents must include: the name of the significant guidance document, any document identification number, and issuance and revision dates and must identify significant guidance documents that have been added, revised or withdrawn in the past year. New significant guidance documents and their links should be added to this list within 30 days from the date of their issuance, but ideally as soon as possible. (Sec. III(1) of the Bulletin).

The lists should be maintained in a manner consistent with OMB policies for agency public Web sites and information dissemination. As agencies develop or revise significant guidance documents, they should organize and catalogue their significant guidance documents to ensure users can easily browse, search for, and retrieve significant guidance documents on agency Web sites. To further assist users in understanding agency guidance documents and the relationship of the guidance documents to current or proposed Federal regulations, agencies should also link their significant guidance document lists to Regulations.gov.

The agency must also provide, on its Web site, the name and contact information for the office or offices designated by the agency to receive and address complaints by the public that the agency is not following the procedures in the Bulletin or is improperly treating a significant guidance document as a binding requirement. (Sec. III(2)(b) of the Bulletin). The agency's Regulatory Policy Officer should ensure that these individuals respond promptly and appropriately to any such complaints

10. Can a subcomponent of an agency establish a separate Web site listing guidance documents and/or designate more than one office to receive and address complaints from the public on the guidance documents?

The Bulletin allows for an electronic list of significant guidance documents to be posted on a component or subagency Web site as long as the agency maintains a link to this list on its Web site. In this case, both the component or subagency Web site and the agency Web site must be maintained in a manner consistent with OMB policies for public Web sites and information dissemination.

The Bulletin requires the agency to designate an office (or offices) to receive and address complaints by the public that the agency is not following the procedures in the Bulletin or is improperly treating a guidance document as a binding requirement. Accordingly, the Bulletin permits an agency to establish one or more such offices, at its discretion. The agency shall provide the name and contact information for the office(s) on its Web site.

11. What requirements does the Bulletin establish -- for public comments and for Agency responses to those comments -- for "economically significant" guidance documents?

When the agency prepares a draft of an economically significant guidance document, the agency must publish a notice in the Federal Register announcing that the draft guidance document is available for comment and otherwise make it publicly available (e.g., by maintaining a hard copy, posting the draft on its Web site and ensuring that persons with disabilities can reasonably access and comment on the guidance). The Federal Register notice should explain how to submit comments and establish a period of time for the receipt of comments. Prior to or upon announcing availability of the draft guidance document, the agency should establish a public docket. Agencies should provide a link on their Web site from the guidance document to the public comments. In response to comments received on economically significant guidance documents, the agency also must prepare a response-to-comments document and make it publicly available in hard copy and on its Web site. (Sec. IV of the Bulletin). Further, in their requests for public comment, agencies should state that the guidance document does not have the force and effect of law.

12. What requirements does the Bulletin establish -- for public comments and for Agency responses to those comments -- for "significant" guidance documents?

The Bulletin does not require agencies to publish draft significant guidance documents for public comment prior to final issuance. However, each agency should have adequate procedures for handling public comments on significant guidance documents after they are published. Each agency must establish and clearly advertise on its Web site a means for the public to submit comments electronically and to provide a way for the public to request electronically that significant guidance documents be issued, reconsidered, modified or rescinded. However, unlike for economically significant guidance documents, the agency is not required to prepare a formal response-to-comments document. (Sec. III(2)(a) of the Bulletin).

The agency should provide, to the extent appropriate and feasible, a Web site link from the significant guidance document to the public comments filed on it. While agencies must comply with the Federal Records Act, agencies are not required to display public comments on their Web sites indefinitely. Accordingly, it would be appropriate for agencies to develop procedures for posting and maintaining the comments on the agency's Web site for a specified and reasonable period of time so as to enable interested members of the public to view the comments (and perhaps to offer their own comments in reply), and then to withdraw the comments from the Web site.

Should an agency determine that publishing a draft for public comment would be beneficial, they should provide a link from the significant guidance document to the public comments filed on it.

13. Should agencies use Regulations.gov to process public comments for guidance documents?

Yes. Agencies must use Regulations.gov to process public comments for economically significant guidance documents. Regulations.gov may also be used to process public comments for significant guidance documents. If your agency has not yet migrated to Regulations.gov, your agency can utilize existing processing capabilities. Your agency's Chief Information Officer can assist in scheduling and obtaining this service.

14. Under the Bulletin, what should an agency do if it believes that it would not be feasible or appropriate for the agency to provide the public with advance notice of, and an opportunity to comment on, an economically significant guidance document before the agency issues the guidance in final form?

An agency head or the Regulatory Policy Officer, in consultation with the OIRA Administrator, may identify a particular economically significant guidance document or class of economically significant guidance documents for which the procedures of Section IV of the Bulletin are not feasible and appropriate. In these circumstances, the agency should nonetheless: (a) publish a notice in the Federal Register announcing that the guidance document is available; (b) post the guidance document on its Web site and make it available in hard copy (or notify the public how they can review the guidance document if it is not in a format that permits such electronic posting with reasonable efforts); and (c) seek public comment when it issues or publishes the guidance document. If the agency receives comments on an excepted guidance document, the agency should review those comments and revise the guidance document as appropriate.

15. Under the Bulletin, what should an agency do if it needs to issue a significant guidance document to address an emergency situation?

The Bulletin expressly provides for emergency situations or when an agency is obligated by law to act more quickly than would occur under normal review procedures. In those cases, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with the Bulletin. (See also the question in D(22) below concerning how the agency should proceed under the Executive Order when issuing guidance to address an emergency situation.)

16. What are the timelines for meeting the requirements of the Bulletin?

No later than July 24, 2007, agencies must:

- Have developed procedures for the approval of significant guidance documents. Those procedures should ensure that the issuance of a significant guidance document is approved by appropriate senior agency officials (Sec. II(1) of the Bulletin);

- Comply with the standards for guidance documents contained in Section II(2) of the Bulletin;
- Provide for public comment on new economically significant guidance documents and otherwise meet the requirements of Section IV of the Bulletin.
- In accordance with Section III(1) of the Bulletin, provide on their Web sites a list of significant guidance documents promulgated after January 25, 2007.
- Advertise on the Web site a means for public feedback (Sec. III(2)(a) of the Bulletin); and
- Designate an office (or offices) to receive and address complaints by the public. The designated office should be clearly identified on the agency Web site, along with the contact information for the office. (Sec. III(2)(b) of the Bulletin)

No later than August 23, 2007, agencies must:

- Provide a list of significant guidance documents currently in effect and promulgated on or before January 25, 2007 on their agency Web site in accordance with Section III(1) of the Bulletin (and new significant guidance documents and their Web site links shall be added promptly to this list, no later than 30 days from the date of issuance); and
- Identify (and update at the beginning of each calendar year) significant guidance documents on the list that have been added, revised, or withdrawn within the past year, in accordance with Sec. III(1)(b) of the Bulletin.

We encourage the agencies to implement the requirements of the Bulletin sooner, if practicable.

D. Guidance Questions – Applicable to Requirements specific to the Executive Order

17. Under the Executive Order, what is an agency required to do when it wants to issue a "significant" guidance document?

Before an agency promulgates a significant guidance document, the agency must:

(1) Provide to OIRA advance notification of any significant guidance documents; and
(2) Upon the Administrator's request, provide to OIRA the content of the draft guidance, together with a brief explanation of the need for the guidance document and how it will meet that need.

Within ten (10) days of providing such notice to OIRA, OIRA will notify the agency if additional consultation will be required before issuing the guidance. (Sec. 9 of the Executive Order)

The Executive Order assigns responsibility for ensuring compliance with these requirements to the Regulatory Policy Officer.

18. Under the Executive Order, how should an agency provide advance notification to OIRA of a significant guidance document?

As a general rule, no less than 10 days prior to intended dissemination of a significant guidance document, including draft documents that an agency may disseminate for public comment, the appropriate personnel at the agency should work with the OIRA desk officer who handles review of that agency's rules pursuant to Executive Order 12866. At a minimum, for each significant guidance document, the agency should provide the following information to OIRA:

- DEPARTMENT/Subcomponent;
- Title;
- Planned Publication Date;
- Name and Telephone number of the agency official who can answer detailed questions about the guidance document and;
- A brief description of what the agency is intending to do and why, issues associated with the guidance, time pressures, and why the action is important. If the agency received comment on a draft guidance document, include a brief statement of the nature and extent of public comment and the nature and extent of changes made in response to the public comment.

Lengthy or detailed descriptions of the issues listed above are not necessary. Based on these descriptions, OIRA will determine whether the agency should submit the content of the draft guidance.

Please note that these summaries are required only for "significant" guidance documents, which includes "economically significant" guidance documents.

An agency should provide this information to OIRA using the same process that the agency uses to request significance determinations for regulations.

19. What is the next step when the OIRA Administrator determines that additional consultation under the Executive Order is warranted?

If the Administrator determines that additional consultation is warranted, OIRA will review the guidance to ensure that it is consistent with the philosophy and principles of Executive Order 12866, as amended, and will also coordinate review among appropriate Executive branch departments and agencies. Additionally, OIRA will discuss with the agency its compliance with the requirements in the Bulletin that apply to "significant" and/or "economically significant" guidance documents. OIRA will remain in close consultation with the agency until the review is completed and will conduct the review in as expedited a manner as is possible. OIRA will complete its consultative process within 30 days or, at that time, advise the agency when consultation will be complete.

20. How will the OIRA Administrator determine which significant guidance documents are exempt from review under the Executive Order?

The Executive Order gives the OIRA Administrator the authority to exempt any category of agency guidance documents from centralized review. If an agency wishes to request an exemption, it should make such a request to the Administrator who will consider the request in consultation with the agency.

21. What is the time period for consultation with OIRA on significant guidance documents under the Executive Order?

The Executive Order does not specify a time period for review of significant guidance documents. However, as noted above, OIRA will remain in close consultation with the agency until the review is completed and will conduct the review in as expedited a manner as is possible. OIRA will complete its consultative process within 30 days or, at that time, advise the agency when consultation will be complete.

22. What should an agency do, under the Executive Order, if the agency needs to issue a significant guidance document to address an emergency situation?

If an agency needs to issue a significant guidance document to address an emergency situation, the agency should notify OIRA as soon as possible. After the emergency has been addressed, OIRA and the agency will consult on whether further review, including interagency review, is warranted under the Executive Order.

23. How were the Regulatory Principles of Executive Order 12866 amended to apply to guidance documents?

The Executive Order amends the Principles of Regulation (Sec. (1)(b) of the Executive Order) to ensure guidance documents are consistent with the philosophy of Executive Order 12866. Four of the principles are revised to clarify that they apply to guidance. Specifically, the principles, as amended, state [changes in italics]:

- Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of the intended regulation *or guidance document* (Sec. (1)(b)(7) of the Executive Order);
- Each agency shall avoid regulations *or guidance documents* that are inconsistent, incompatible, or duplicative with its other regulations *or guidance documents* or those of other Federal agencies (Sec. (1)(b)(10) of the Executive Order);

- Each agency shall tailor its regulations *and guidance documents* to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the cost of cumulative regulations (Sec. (1)(b)(11) of the Executive Order); and
- Each agency shall draft its regulations *and guidance documents* to be simple and easy to understand with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty (Sec. (1)(b)(12) of the Executive Order).

E. Non-Guidance provisions in Executive Order 13422

24. When does an agency head need to designate its Regulatory Policy Officer?

Under the Order, each agency head was required to designate the agency's Regulatory Policy Officer no later than March 19, 2007. If your agency has not done so, please notify Margaret Malanoski at (202) 395-3122 or mmalanos@omb.eop.gov of this designation immediately. Further, the agency head must annually update OMB on the status of this designation.

Independent agencies are encouraged to appoint a Regulatory Policy Officer.

25. What changes does the Executive Order make to the appointment of the Regulatory Policy Officer?

The Order requires the Regulatory Policy Officer to be one of the agency's Presidential appointees. (Sec.6(a)(2) of the Executive Order) For many agencies, this will not be a change, because their Regulatory Policy Officers have already been Presidential appointees. These Presidential appointees will report to the heads of their agencies in carrying out their role as the agency's Regulatory Policy Officer, as they do when carrying out their other responsibilities and as the Regulatory Policy Officers have previously done.

26. Can the agency head designate as the Regulatory Policy Officer an agency employee who serves in a position for which the agency head (not the President) is the appointing official?

No. The agency head may designate the agency's Regulatory Policy Officer from among those agency positions whose appointment is vested by law in the President. Such "political appointees" as Schedule C and non-career SES employees are appointed by the agency head, not by the President, and thus they may not be designated as the agency's Regulatory Policy Officer.

27. If there is a vacancy in the Presidentially-appointed position that the agency head has designated as the Regulatory Policy Officer, may the person who is serving in an "acting" capacity in that position be the Regulatory Policy Officer?

Yes. If a person who is not a Presidential appointee is serving in the acting capacity in a position that is Presidentially-appointed (PA), the amended Executive Order does not require an agency head to designate another official to serve as the Regulatory Policy Officer when a vacancy exists in the PA position that is designated as the Regulatory Policy Officer. Such a requirement to change the designation would be disruptive of agency operations.

28. Are independent regulatory agencies required to designate a Presidential appointee as a Regulatory Policy Officer?

No. Independent regulatory agencies are not subject to the requirement in Section 6(a)(2) of the Executive Order regarding the designation of Regulatory Policy Officers. However, the heads of independent regulatory agencies may decide to designate a Regulatory Policy Officer in order to meet the requirements for the Regulatory Plan (Sec. 4(c) of the Executive Order). We encourage independent agencies to do so.

29. Will the Regulatory Policy Officers continue to report to their agency heads, as they did under Executive Order 12866 prior to its recent amendment?

Yes. The deletion of the "report to the agency head" language by the recent Executive Order does not change the fact that the Regulatory Policy Officer reports to the agency head. As before, the agency head continues to be the official who designates the agency's Regulatory Policy Officer. The Regulatory Policy Officer will continue to report to the agency head in performing that role, as well as in performing his or her other responsibilities.

30. Does the agency need to establish a Regulatory Policy Office, in addition to the agency head designating a Regulatory Policy Officer?

No. The reference in Executive Order 13442 to a Regulatory Policy "Office" was a typographical error. This is in fact another reference to the Regulatory Policy Officer.

31. What changes does the Executive Order make to the responsibilities of the Regulatory Policy Officer?

Under the Executive Order, the Regulatory Policy Officer must:

- Personally authorize the commencement of rulemakings and the inclusion of rulemakings on the Regulatory Plan, unless they are otherwise authorized by the head of the agency. (Sec. 4(c) of the Executive Order); and

- Ensure that the agency provides OIRA with advance notification of and an opportunity to review any significant guidance documents prior to their promulgation. (Sec. 9 of the Executive Order).

Of course, it is assumed that these requirements will be implemented in a way that complies with all applicable laws.

32. When does a rulemaking "commence" for the purpose of meeting the new requirement for the Regulatory Policy Officer's (or the agency head's) authorization of the agency's "commencement of a rulemaking"?

The point at which a rulemaking commences may vary from one agency to the next, depending on each agency's procedures and practices, and may vary from rulemaking to rulemaking. As a general matter, a rulemaking commences when the agency has decided as an institutional matter that it will engage in a rulemaking. At the latest, the rulemaking will commence when the rulemaking receives a Regulation Identification Number (RIN).

33. What are the new requirements for the Regulatory Plan?

As noted above, the Executive Order requires the Regulatory Policy Officer (or the head of the agency) personally to authorize the commencement of rulemakings and the inclusion of rulemakings on the *Regulatory Plan*.

As has always been the case under Executive Order 12866, regulations identified in Part II of the *Plan* should, to the extent possible, include preliminary estimates of the anticipated costs and benefits of each rule. The change made by Executive Order 13422 is that each agency providing such estimates must sum-up these individual rule-by-rule estimates into a combined aggregate estimate of the costs and benefits of all its regulations planned for each calendar year or thereafter. (Sec. 4(c) of the Executive Order). The summation methodology should be internally consistent and transparent. The aggregate figures should be provided in a manner that allows for the public to easily understand the overall impact of the planned regulatory actions.

In summarizing the legal basis for each action, agencies must provide a specific citation for the statute, order, or other legal authority for each planned regulation. In particular, with regard to legal deadlines for completion of rulemakings, it will be necessary for agencies to provide full and specific information sufficient to identify in detail the source of any deadline requirements.

34. Do the revisions to the Principles of Regulation, specifically those in Section 1(b)(1) related to "market failure," require agencies to provide more or different information to OIRA when submitting a regulation for review?

The Executive Order clarifies in the Principles of Regulation (Sec. 1(b)(1) of the Executive Order) that: "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it

intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem."

This is not a substantive change to the Regulatory Principles of Executive Order 12866. Rather, this change makes clear that agencies must state "in writing" the problem the regulation seeks to address. Many agencies already provide this information in their preambles and, for those agencies, this should not represent any change.

Please note that the revision to the principle does not prescribe or limit the agencies' written rationale exclusively to "market failure, though that issue should be addressed where it is applicable. The language from the principle explicitly recognizes that there may be other "specific problems that [an agency] intends to address…that warrant new agency action." In addition, the language that expressly directs Federal agencies to "promulgate . . . such regulations as are required by law, [or] are necessary to interpret the law" has not been amended and so it continues to apply. Agencies should continue to set forth the appropriate basis for any proposed regulatory action.

35. Does the Executive Order require an agency to consider the use of formal rulemaking?

No. The Executive Order instead reminds agencies that they may, in consultation with OIRA, consider whether to use formal rulemaking procedures under the Administrative Procedure Act (APA) for the resolution of complex determinations. This is a reminder to agencies of an authority that they have long had, and that remains available to them, under the APA. Some agencies have utilized this authority and may want to consider doing so in the future, and other agencies may identify situations in which it could be beneficial.

* * * *

Further Questions

With whom should agency staff consult about questions concerning the Executive Order and the Bulletin?

If your staff has questions concerning the Executive Order or the Bulletin, please contact Margaret Malanoski in OIRA ((202) 395-3122 and mmalanos@omb.eop.gov.)

Executive Order 12866

(September 30, 1993, 58 F.R. 51735, as amended by Executive Order 13258, February 26, 2002, (67 F.R. 9385 (February 28, 2002)), as amended by Executive Order 13422, January 18, 2007, (72 F.R. 2763 (January 23, 2007)))

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today. With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies. Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Statement of Regulatory Philosophy and Principles.

(a) The Regulatory Philosophy. Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) The Principles of Regulation. To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) ~~Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.~~ *Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.*

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation *or guidance document.*

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as

appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.
(10) Each agency shall avoid regulations *and guidance documents* that are inconsistent, incompatible, or duplicative with its other regulations *and guidance documents* or those of other Federal agencies.
(11) Each agency shall tailor its regulations *and guidance documents* to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.
(12) Each agency shall draft its regulations *and guidance documents* to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

§ 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) The Agencies. Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations *and guidance documents* and assuring that the regulations *and guidance documents* are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) The Office of Management and Budget. Coordinated review of agency rulemaking is necessary to ensure that regulations *and guidance documents* are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President and regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations *and guidance documents*, as provided by this Executive order.

(c)Assistance. In fulfilling his responsibilities under this Executive order, the President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President may, from time to time, consult.

§ 3. Definitions. For purposes of this Executive order:

(a) "Advisors" refers to such regulatory policy advisors to the President as the President may from time to time consult, including, among others: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the

President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Director of the Office of Science and Technology Policy ; (7) the Deputy Assistant to the President and Director for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Chairman of the Council on Environmental Quality and Director of the Office of Environmental Quality; (12) the Assistant to the President for Homeland Security; and (13) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.
(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" ~~or "rule"~~ means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations ~~or rules~~ issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;
(2) Regulations ~~or rules~~ that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;
(3) Regulations ~~or rules~~ that are limited to agency organization, management, or personnel matters; or
(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final ~~rule or~~ regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a ~~rule~~ [?] *regulation* [?]that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

(g) "Guidance document" means an agency statement of general applicability and future effect other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.

(h) "Significant guidance document" --

(1) Means a guidance document disseminated to regulated entities or the general public that, for purposes of this order, may reasonably be anticipated to:

(A) Lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(B) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(C) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or

(D) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order; and

(2) Does not include:

(A) Guidance documents on regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(B) Guidance documents that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(C) Guidance documents on regulations that are limited to agency organization, management, or personnel matters; or

(D) Any other category of guidance documents exempted by the Administrator of OIRA.

§ 4. Planning Mechanism. In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law:

(a) ~~Agencies' Policy Meeting. Early in each year's planning cycle, the Director shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.~~*The Director may convene a meeting of agency heads and other government personnel as appropriate to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.*

(b) Unified Regulatory Agenda. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) The Regulatory Plan. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. ~~The Plan shall be approved personally by the agency head and shall contain at a minimum:~~*Unless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office, and the Plan shall contain at a minimum:*

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits *of each rule as well as the agency's best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities*;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order, *and specific citation to such statute, order, or other legal authority*;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies and the Advisors.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly

notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency and the Advisors.
(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies and the Advisors.
(6) The Director may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.
(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) Regulatory Working Group. Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility and the Advisors. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Director on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) Conferences. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

§ 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed

circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations:

(a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Director, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

§ 6. Centralized Review of Regulations. The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) Agency Responsibilities. (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. *In consultation with OIRA, each agency may also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations.* Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) ~~Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head.~~*Within 60 days of the date of this Executive order, each agency head shall designate one of the agency's Presidential Appointees to be its Regulatory Policy Officer, advise OMB of such designation, and annually update OMB on the status of this designation.* The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) OIRA Responsibilities. The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive

order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines:

(i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did

not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

§ 7. Resolution of Conflicts.

(a) To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, with the assistance of the Chief of Staff to the President ("Chief of Staff"), with the relevant agency head (and, as appropriate, other interested government officials). Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

(b) Resolution of such conflicts shall be informed by recommendations developed by the Chief of Staff, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

(c) During the Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Chief of Staff shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for

inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

(d) At the end of this review process, the President, or the Chief of Staff acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

§ 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Director, as provided under section 7 of this order. Upon receipt of this request, the Director shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

§ 9. Significant Guidance Documents. *Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notification of any significant guidance documents. Each agency shall take such steps as are necessary for its Regulatory Policy Officer to ensure the agency's compliance with the requirements of this section. Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before the issuance of the significant guidance document.*

~~***§ 9 10. Agency Authority.*** Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by *law*.~~ ***Preservation of Agency Authority.*** *Nothing in*
this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof, including the authority of the Attorney General relating to litigation.

~~***§ 10 11. Judicial Review.*** Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to

improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

§ ~~11~~ 12. Revocations. Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

WILLIAM CLINTON
THE WHITE HOUSE
September 30, 1993.

While on the Home Front

Missing from the *New York Times* of January 19—and for that matter the *Washington Post*—was any attention to an executive order the President issued quietly on Thursday, that achieves a major increase in White House control over domestic government. The executive order, issued without explanation or accompanying press release, appears to be a series of technical amendments to an existing regime by which the White House coordinates the activities of federal agencies adopting regulations. Among its measures, the order

- considerably expands the range of activities embraced by the order, from official regulations having the force to law to less formal policy and interpretations;
- requires agencies to place control over these activities into the hands of a "presidential appointee"—that is, a person whose appointment does not require senatorial confirmation—unless a particular decision of hers is specifically overridden by the agency's senatorially confirmed head;
- requires the agency to consider in addition to its statutory responsibilities issues Congress may not have thought appropriate factors for decision; and
- gives the White House considerable leverage to require the agency to adopt expensive and delaying procedures for considering proposed regulations, that will greatly enhance the effective power of participants in the process - regulated industries who may have White House friends, in particular.

It is perhaps not surprising that, having lost control of Congress, the President is doing what he can to increase his control of the executive branch. President Clinton, when he lost the Congress, also worked to achieve by regulation what he could not expect to do legislatively. Much more law is made today by regulation than legislation, in any event. But yesterday's steps reflect the view we have seen in connection with the war in Iraq as well, that the President is a law unto himself, entitled to act without particular regard to Congress's wishes.

Senatorial confirmation gives agency heads a relationship with Congress as well as the White House. They are the ones Congress's laws empower to decide regulatory matters. Given the enormous range of governmental responsibilities today, it is even less thinkable now than it was two centuries ago that these decisions, in their detail, are for the President—he may consult, he may oversee, but the law places decisional authority in them. President Andrew Jackson had to fire two Secretaries of the Treasury before he could find an Acting Secretary willing to move government funds out the United States Bank; he and they understood that the decisional authority rested in them—and the Senate promptly refused to confirm the Acting Secretary's nomination. Now a presidential ukase places decisional authority in the hands of a person with whom the Senate has no relationship; should the President fire and wish to replace that person, there will be no such political price to pay.

Congress also sets the factors that an agency is to consider in reaching regulatory decisions. It may quite deliberately exclude some possibly relevant factors from agency consideration. A few years ago, for example, the Supreme Court found that the *Clean Air Act* did not authorize the Environmental Protection Agency to consider costs. The new factors the executive order makes potentially decisive, in the hands of a person answering only to the President, effectively amend the law as the President—but not the Congress—wishes.

Congress has been chary of requiring the complex procedures the executive order appears to place in White House control. Rule-makings using them, in substantial control of the participants as ordinary rule-makings are not, can extend for years. A quarter-century ago, when the DC Circuit had imposed similar requirements judicially, the Supreme Court said emphatically that any such decision was for Congress. Now the President has effectively appropriated that decision for himself—and his political friends.

We have long been a nation under law. The war emergency has placed that proposition under considerable strain. If the President's law-transcending claims, however wrong, can be understood in that context, they should not be tolerated when, as now, they emerge in stealth documents, in the ordinary context of law-administration.

Dr. Peter L. Strauss
Betts Professor of Law
Columbia Law School

Bush Order Limits Agencies' 'Guidance'

BY CINDY SKRZYCKI
TUESDAY, JANUARY 30, 2007; PAGE D01

On Jan. 18, when the headlines in the United States focused on the war in Iraq, the new Democratic Congress and actress Lindsay Lohan's alcohol problem, the Bush Administration rewrote the book on federal regulation.

President Bush issued an executive order curbing the power of agencies to regulate industry through "guidance"—informal advice that falls short of official rules yet can still cost companies millions of dollars to comply with. The order, which also calls on agencies to project the cost of new rules, among other demands, gives the White House more power to review how they write standards to regulate corporate behavior.

The amendments are "the most serious attempts by the executive branch to control the regulation mills of the hundreds of federal agencies," said William Kovacs, Vice President of Environment, Technology and Regulatory Affairs at the U.S. Chamber of Commerce, the Nation's largest business lobby.

The story behind those changes illustrates how important the competing sides consider rule writing. Even subtle word changes can have significant effects on what the chemical, oil, home-building, pharmaceutical and other highly regulated industries must spend.

"It's another thumb on the scale," said Sally Katzen, who headed the Office of Information and Regulatory Affairs, the top regulatory job, in the White House Office of Management and Budget during the Clinton Administration. "There will be more boxes to check, more I's to dot, more T's to cross and more analysis."

Federal agencies issue guidance to interpret key policy and technical questions, often at the request of industry. The Labor Department's Occupational Safety and Health Administration, for example, issued 574 guidance documents between 2001 and 2005, many directed at the construction industry.

Though the guidance isn't legally binding, companies pay close attention to it. More than 30 individuals and groups, including those representing funeral directors and ornithologists, filed comments about "good guidance practices" for a bulletin issued with the executive order.

Some, such as the American Chemistry Council based in Arlington, said it was "frequently beneficial" for agencies to have the flexibility to issue guidance without a formal rule-writing process. Still, the council and most others who filed comments backed the plan to rein in the practice because of concern that guidance at times amounted to back-door rule writing.

Guidance should be subject to oversight by the OMB and public notice and comment, they argued.

General Electric, the world's second-largest company by market value, said the Environmental Protection Agency issued guidance on how to clean up toxic chemicals, which a court ruled in 2002 was actually a "legislative rule." The Fairfield, Conn., company recommended that agencies be required to maintain a list of all guidance documents on their web sites.

Sanofi-Aventis, France's largest drug-maker, said guidance documents "can have significant impact on our business as well as on the ultimate lives of our customers—patients."

The Paris company, whose U.S. headquarters is in Bridgewater, N.J., recapped an experience in which the Centers for Medicare and Medicaid Services switched its payment policy on four drugs last year, after the final rule had been approved.

Bush's executive order told agencies they must submit to the White House budget office for review any guidance that has an impact of $100 million or more on the economy and make such significant interpretations available to the public for comment.

Kovacs said the Chamber's complaint about guidance "was one of the first issues we talked about" with John Graham, the Administration's first regulatory czar at the OMB.

Another change requires agencies to state in writing "the specific market failure" that it intends to cure with a new rule. Insufficient competition can be a sign of such a failure, OMB officials said. Or the government may have to order nutritional labeling because there otherwise would be a lack of information for consumers.

The market-failure concept has taken on new emphasis with the Bush Administration. The President nominated Susan Dudley, the former head of the regulatory program at the Mercatus Center, a free-market-oriented research group at George Mason University in Arlington, to replace Graham in the top regulatory job at the

OMB. Dudley wasn't confirmed by the Senate in the last Congress and is now a top aide in the budget office.

Public Citizen, a District nonprofit group that monitors regulation, charged that Dudley will use a market-failure standard to create economic barriers to protecting the public.

Under the Bush executive order, regulators also now will have to estimate the total costs and benefits of planned rules. And the process will be overseen in each agency by a political appointee, another provision that public interest groups oppose.

"There is no question who this panders to," said Rena Steinzor, a University of Maryland Law Professor who is critical of administration regulatory policy. "It's something business has wanted."

Jeffrey Rosen, OMB's general counsel, said: "Simply put: What we are doing here is 'good government.' We are building upon a process that has been used by presidents of both parties to try to institutionalize best practices."

Criticism of the changes is "a tempest in a teapot," said Paul Noe, an adviser to Graham who is now a Washington lawyer. "The executive order promotes better-informed and more accountable regulatory decisions."

Congress should be paying attention to the President's action because he is usurping the authority the lawmakers gave the agencies to regulate, according to Peter Strauss, a Professor at Columbia University Law School.

"It's maybe not surprising that having lost control of the Congress, the President is doing what he can to increase control of the Executive Branch," Strauss said.

Cindy Skrzycki is a regulatory columnist with *Bloomberg News.* She can be reached at *cskrzycki@bloomberg.net.*

Bush order on government regulation stirs debate

BY TABASSUM ZAKARIA
REUTERS

TUESDAY, JANUARY 30, 2007; 4:28 PM

WASHINGTON (Reuters)—An order signed by President George W. Bush on the oversight of thousands of government regulations issued every year was praised by business as a step toward controlling an unwieldy process but criticized by others as potentially a loser for consumers.

The White House said the executive order signed by Bush on January 18 makes a senior official in each agency accountable for the regulations it issues and provides greater openness by ensuring that "guidance" documents issued to businesses are available to the public.

Business groups say the order should help businesses which have to wade through a myriad of regulations, sometimes conflicting ones from different agencies, by making one person in each agency in charge of overseeing the regulations issued.

Consumer groups say the public would lose out because the order could slow the process by which regulations in the public interest such as pollution controls would be issued, and puts the process under the control of an official appointed by the President.

Jeffrey Rosen, counsel at the White House Office of Management and Budget, called the criticism a "mistaken argument" and said the basic regulatory process in the order has been in place over both Democratic and Republican administrations.

"The basic framework is the same," he said of the order which amended an order issued by President Bill Clinton in 1993.

"This is just another tool for industry and their allies in the Bush White House to slow down and prevent agencies from getting things done to protect the public," said Robert Shull, deputy director for auto safety and regulatory policy at Public Citizen.

The order requires agencies use a standard of "market failure," which means determining whether private markets can correct a social problem like pollution on their own, in deciding whether government needs to step in, he said.

Shull said that was too high a bar to meet as the new Democratic-controlled Congress prepares to take on issues like global warming and fuel economy.

Rosen said the new order better defines the term market failure from Clinton's order. On consumer advocate concerns like pollution, "the clarification actually helps," because it would be a legitimate basis for regulation, he said.

Consumer groups expressed concern about the order's requirement that the regulatory oversight officer at the agencies be appointed by the President.

"This is really just another way of the White House getting its fingers in all of the agencies, manipulating all of their policies and all of their priorities in a way that Congress never intended," Shull said.

Rosen said it meant more accountability. "If you want to know who's responsible for regulatory decisions, here's who it is and it's a presidential appointee, meaning it's somebody very senior," he said. "It's a way of identifying some accountability."

The regulatory process puts out about 4,000 regulations every year in addition to the 192,000 regulations that exist, said Bill Kovacs, Vice President of Regulatory Affairs at the U.S. Chamber of Commerce.

"Imagine yourself being a small business and trying to comply on any given day with labor standards, health standards, pension standards, environmental standards," Kovacs said. "So people are trying to find some way to get control over the process."

Union of Concerned Scientists
Citizens and Scientists for Environmental Solutions

February 12, 2007

To: House Committee on Science and Technology, Subcommittee on Investigations and Oversight
From: Francesca Grifo, Senior Scientist, Union of Concerned Scientists
Re: Amendments to Executive Order 12866

By centralizing decision-making power in the White House, new amendments to Executive Order 12866 endanger the independence of federal science. The amendments insulate the executive branch from congressional accountability and oversight at the time when Congress is investigating the politicization of science and its effect on the American people.

The amendments are the latest chapter in an ongoing effort to sideline independent science from the decision-making process. Good government and a functioning democracy requires public policy decisions be informed by independent science. The executive order amendments make it easier for political appointees to manipulate, distort, and suppress the work of government scientists. This subterfuge rulemaking cannot be allowed to continue. Congress must act to restore scientific integrity and checks and balances to the federal policy making process by preventing the implementation of these amendments.

Over the past six years, the Bush administration has attempted to marginalize the way in which science informs federal policy making. This has been accomplished by two dominant methods: first, by interfering with the scientific process and second, by changing the way in which scientific information is incorporated into the decision making process.

Political Interference in Science
Federal government science has been distorted, manipulated, and suppressed on everything from childhood lead poisoning to toxic mercury emissions, with serious consequences for our health, safety, and environment. UCS has documented scores of specific examples of abuse in its "*A to Z Guide to Political Interference in Science (Attached as Appendix A)*. Political interference in science can take many forms—from censorship and suppression of federal science to dissemination of inaccurate science-based information to the manipulation of scientific advice.

The problem of political interference has surfaced in many federal science agencies, whose staff work on topics ranging from airborne bacteria to endangered species. The Union of Concerned Scientists has surveyed scientists at nine federal agencies, including the Food and Drug Administration, the U.S. Fish and Wildlife Service, the National Oceanic and Atmospheric Administration's Fisheries Division, and several agencies with scientists who work on climate change.

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Of the more than 1,800 federal scientists across nine agencies who have responded to questionnaires about this issue, 699 scientists (39 percent) report that they fear retaliation for openly expressing concerns about their agency's mission-driven work. 432 scientists from five agencies reported that they were not able to publish work in peer reviewed journals if it did not adhere to agency policies.

In a survey of climate scientists alone, 150 climate scientists reported *personally experiencing* at least 435 occurrences of political interference in their work over the past five years. This number should be zero. Forty in-depth interviews with climate scientists revealed restrictive media policies that impaired timely release of information to help policy makers and the public understand global warming science. Scientists reported unnecessary delays and misrepresentation of press releases on new research, requirements for pre-approval for press interviews, and agency public affairs officials listening in on interviews between journalists and scientists.

The scientific community has spoken out strongly against these practices. More than 11,500 scientists, including 52 Nobel laureates, 194 members of the National Academies of Science, and science advisors to both Republican and Democratic presidents dating back fifty years, have signed a statement condemning this interference and calling for a restoration of scientific integrity to federal policy making.

Altering the Decision-Making Process

More insidious are attempts to limit transparency and cut out science from the way federal agencies make decisions that allow them to meet their public service missions. One notable example of how this process has been altered is with the promulgation of a new air pollution protection rulemaking process under the National Ambient Air Quality Standards (NAAQS).

The Clean Air Act requires the Environmental Protection Agency to create NAAQS for harmful pollutants using the best available science. For decades, EPA staff scientists have worked with the independent Clean Air Science Advisory Committee (CASAC) to review the latest studies and recommend appropriate standards. Under these old rules, staff scientists worked with CASAC to create a scientific assessment of risks and recommend appropriate standards. Only after the scientific review was complete would the Administrator create the final policy.

Despite this process, the recommendations of scientists have not always been heeded. In 2005, EPA Administrator Stephen Johnson overruled a nearly-unanimous recommendation from scientific advisors that the NAAQS for fine particulate matter be strengthened; Johnson instead chose to maintain a standard that does not adequately protect public health. In an unprecedented move, CASAC wrote a letter to Administrator Johnson to re-explain the science behind their recommendations and to urge him to reconsider the proposed standards. The CASAC members alleged that the EPA had "twisted" or "misrepresented" the panel's recommendations on a number of issues related to the proposed standards.

Perhaps to avoid future negative attention from setting standards that are not based on the best available science, in December 2006 the EPA announced a new policy for setting the NAAQS which removes the independent assessment by scientific experts and injects political determinations much earlier in the decision-making process. Under these new rules, high-level political appointees are involved right from the start, working with staff scientists to create a document containing "policy-relevant science" that "reflects the agency's views" instead of the independent scientific paper that staff scientists have put together in the past. The new rules closely follow recent recommendations from the American Petroleum Institute.

CASAC is entirely cut out of the process until after the EPA has announced its proposed standard, when they are allowed to comment just like any other member of the public. While recognizing that the NAAQS process is often too slow and in need of revision, CASAC, criticized the new process as "no less time-consuming and likely more resource-intensive."

Impact of the Amendments
The new rules would place political appointees deeper inside federal scientific agencies where they could more easily prevent inconvenient science from ever seeing the light of day. Rather than upholding the work of its federal scientists and shielding it from political interference, this new rule will place an added layer of political sign-off in agency work.

In the near future, the federal government is charged with making many science-based decisions. The Environmental Protection Agency will set standards for pollution from lead and ozone. The U.S. Fish and Wildlife Service will make determinations regarding what species should be protected under the Endangered Species Act. The Occupational Safety and Health Administration will create regulations that protect the health and safety of workers. Congress and federal agency leaders should implement reforms that will prevent the continued interference with science for political purposes and allow appropriate scientific input into public policy making.

This Congress has already shown interest in holding the administration accountable for its abuse of the scientific process. Congress held two hearings in as many weeks—one in the House Oversight and Reform Committee and another in the Senate Commerce, Science, and Transportation Committee—to investigate allegations that federal scientists face political barriers in communicating their work outside their agencies.

All branches of government must have access to independent scientific advice. The thousands of scientists employed by the federal government represent a tremendous resource. Without access to the best available science on climate change and other issues, the public's understanding will suffer, and our leaders will be unable to make fully informed decisions about our health, safety, and environment.

Public Citizen

Latest White House Power Grab Puts Public at Risk

Problems of the Jan. 2007 Executive Order and Bulletin on Guidance

January 2007

The White House released a double whammy attack on the public interest on Jan. 18, 2007: (1) a new executive order increasing burdens on the regulatory process, and (2) a final bulletin creating new burdens on agencies ability to inform the public. Together, this double whammy is an enormous challenge to the ability of the federal government to protect and inform the public.

Market Failure... and New Excuses for Failing the Public

The White House already demanded, under Exec. Order No. 12,866 (1993), that agencies state the reason for a new regulation in an economic impact assessment. The new Bush executive order now changes the language, putting the spotlight on "market failure" as the chief rationale — and adding that the purpose of the justification is "to enable assessment of whether any new regulation is warranted."

Exec. Order No. 12,866	Revised Text
Each agency shall identify	Each agency shall identify in writing
the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action)	the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action,
as well as assess the significance of that problem.	as well as assess the significance of that problem,
	to enable assessment of whether any new regulation is warranted.

Market failure is an economics term describing situations in which private markets, left to themselves, fail to bring about results that the public needs. This order, however, will be enforced by Susan Dudley, the radical extremist that the White House is setting up for a recess appointment to become the administrator of the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget. Based on an evaluation of Dudley's record in a report released last year, Public Citizen has concluded that, in her hands, the market failure provision will become a barrier to the protections that the public needs.

Deputy Dudleys in Every Agency

Although Congress delegates power directly to the agencies themselves, thereby diffusing authority throughout the executive branch and preventing any single office from becoming all-powerful, the White House has claimed yet more power to control agencies and distort regulatory policy with political goals. The new executive order commands every agency to designate a presidential appointee to serve as the "Regulatory Policy Officer." Agencies will not be allowed to add new regulatory initiatives to their annual plans without the approval of the new officer.

Putting Industry Costs Above the Public Interest

The new order requires agencies to develop annual plans for upcoming rulemakings that identify "the combined aggregate costs and benefits of all ... regulations planned for that calendar year to assist with the identification of priorities." This new requirement will make cost/benefit analysis the central factor in setting priorities for needed protections of the public interest. These cost/benefit analyses are notoriously biased against regulation, especially long-term goals such as preventing global warming or cancers that manifest years after exposure to toxic substances.

From Guidance to Darkness

The executive order and the new bulletin on guidance work together to create a new bureaucratic bottleneck that would slow down agencies' ability to give the public information it needs.

Guidance	Significant Guidance
agency policy other than a rulemaking which sets forth • a policy on a statutory issue • a policy on a regulatory issue • a policy on a technical issue • an interpretation of a statutory issue • an interpretation of a regulatory issue	guidance which • leads to an annual effect of $100 million or more or materially and adversely affects the economy • creates inconsistencies with another agency's activities • materially alters budgetary impact of grants, entitlements, etc. • raises novel legal or policy issues • implicates the president's priorities

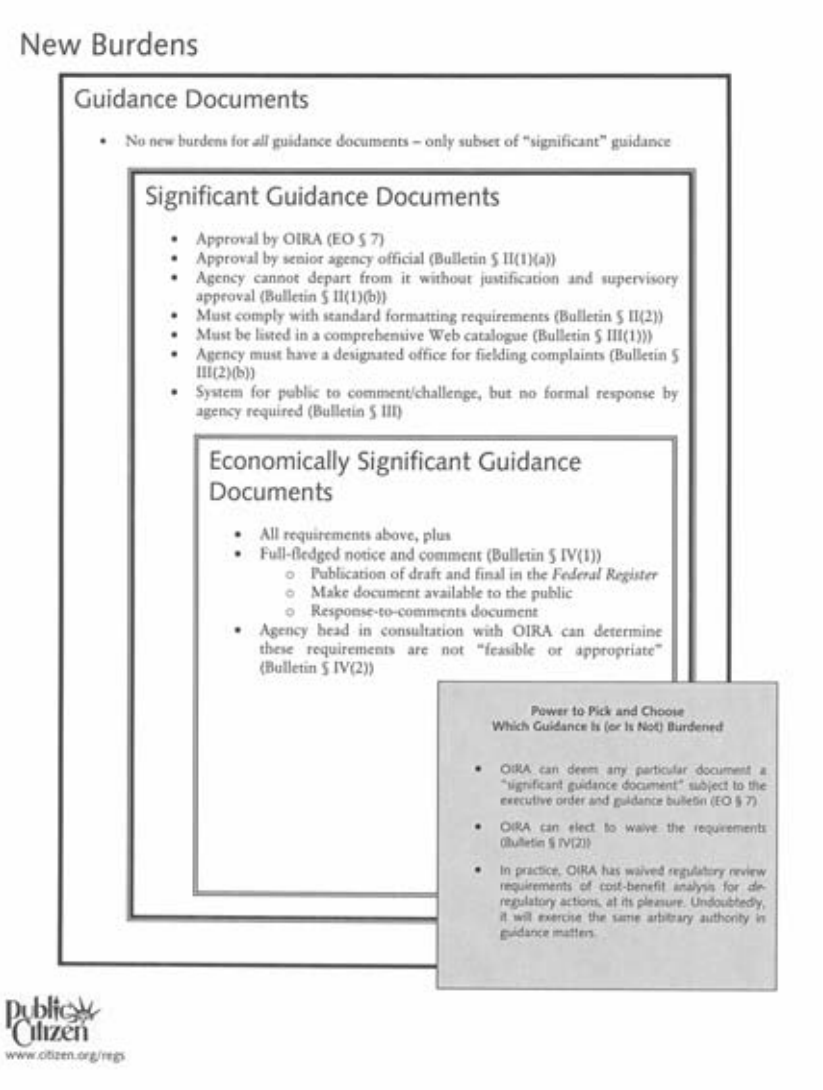
The bulletin requires significant guidance to be approved by a senior-level agency official, and the executive order adds another layer of review by the White House itself. By requiring White House approval of important guidance, the White House will insert its political agenda and pro-business bias into every level of agency policy, so that our federal government will handcuff itself instead of the companies that violate the law and put the public in danger.

The bulletin also requires the agencies to create a Web page listing all significant guidance and creating a public challenge process, for industry to demand changes to the policy statements, interpretations, and so on that it opposes.

So Much for the New Congress

The upshot of this whole executive order is that the White House is already working to undermine not just agencies but also the new Congress' ability to protect the public. Whatever gains might come to consumers and other public interest sectors in the 110th Congress are already vulnerable to being rendered meaningless by the powers the White House is giving itself.


Definitions
Guidance Documents
agency policy other than a rulemaking which sets forth
a policy on a statutory issue
a policy on a regulatory issue
a policy on a technical issue
an interpretation of a statutory issue
an interpretation of a regulatory issue
Significant Guidance Documents
A guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:
Lead to an annual effect of $100 million or more
Adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities
Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency
Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof
Raise novel legal or policy issues arising out of legal mandates, the president's priorities, or the principles set forth in this executive order
Economically Significant Guidance Documents
A significant guidance document disseminated to regulated entities or the general public that may reasonably be anticipated to:
lead to an annual effect on the economy of $100 million or more or
adversely affect in a material way the economy or a sector of the economy,
except that economically significant guidance documents do not include guidance documents on Federal expenditures and receipts.
Excluded
from the Bulletin only:
legal advisory opinions for internal Executive Branch use and not for release;
litigation and enforcement materials;
speeches and press materials;
congressional correspondence;
grant solicitations;
in re government facilities;
internal guidance documents directed solely to other Federal agencies
from the EO only
guidance on regs produced from formal (trial-like) rulemaking
from both
purely internal agency policies;
military, foreign affairs (except in re procurement or import/export of non-defense articles and services);
any other category exempted by agency head in consultation with the OIRA Administrator.
Public Citizen
www.citizen.org/regs


New Burdens
Guidance Documents
No new burdens for all guidance documents – only subset of "significant" guidance
Significant Guidance Documents
Approval by OIRA (EO § 7)
Approval by senior agency official (Bulletin § II(1)(a))
Agency cannot depart from it without justification and supervisory appeoval (Bulletin § II(1)(b))
Must comply with standard formatting requirements (Bulletin § II(2))
Must be listed in a comprehensive Web catalogue (Bulletin § III(1)))
Agency must have a designated office for fielding complaints (Bulletin § III(2)(b))
System for public to comment/challenge, but no formal response by agency required (Bulletin § III)
Economically Significant Guidance Documents
All requirements above, plus
Full-fledged notice and comment (Bulletin § IV(1))
Publication of draft and final in the Federal Register
Make document available to the public
Response-to-comments document
Agency head in consultation with OIRA can determine these requirements are not "feasible or appropriate" (Bulletin § IV(2))
Power to Pick and Choose Which Guidance Is (or Is Not) Burdened
OIRA can deem any particular document a "significant guidance document" subject to the executive order and guidance bulletin (EO § 7)
OIRA can elect to waive the requirements (Bulletin § IV(2))
In practice, OIRA has waived regulatory review requirements of cost-benefit analysis for de-regulatory actions, at its pleasure. Undoubtedly, it will exercise the same arbitrary authority in guidance matters.
Public Citizen
www.citizen.org/regs

AMENDING EXECUTIVE ORDER 12866: GOOD GOVERNANCE OR REGULATORY USURPATION? PART II

THURSDAY, APRIL 26, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:10 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL,
RANKING MEMB

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

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Subcommittee on Investigations & Oversight

Hearing on

"Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part II"

2318 Rayburn House Office Building

Thursday, April 26, 2007
10:00 a.m. – 12:00 p.m.

Witness List

Panel 1

Mr. Steve Aitken
General Counsel for the Office of Information and Regulatory Affairs, Office of Management & Budget

Panel 2

Professor Peter Strauss
Columbia University School of Law

Dr. Robert Hahn
Executive Director, AEI-Brookings Joint Center for Regulatory Studies

Dr. Gary Bass
Director, OMB Watch

Professor Richard Parker
University of Connecticut

HEARING CHARTER

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part II

THURSDAY, APRIL 26, 2007
10:00 A.M.–1:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Tuesday, February 13, 2007 the Subcommittee on Investigations and Oversight of the Committee on Science and Technology held a hearing to receive testimony regarding the President's recent amendment to Executive Order 12866. That order provides guidance to agencies for submitting proposed regulations to the Office of Management and Budget (OMB) for pre-approval.

The amendment (Executive Order 13422) expands this process by requiring agencies to submit proposed significant guidance documents for pre-approval. The Order also requires for the first time that agencies identify in writing the specific market failure or problem that warrants the proposed regulation or guidance; that a Presidential appointee in each agency be designated as regulatory policy officer and that officer must approve each regulatory undertaking by the agency.

The February hearing provided significant testimony highlighting several issues. Three bundles of issues emerged as worthy of further work:

1. How was the Executive Order developed and what are the consequences of changes to the language of E.O. 12866?
2. What does the shift to a "market failure" standard for justifying a regulatory proposal mean and how will the annual agency costs of regulations statements be used?
3. Will the change in the status and authority of the Regulatory Policy Officers in the agencies have consequences for transparency in the regulatory process?

Witnesses

To provide insight into these issues, the Subcommittee has invited the following witnesses:

Mr. Steven Aitken, General Counsel at OIRA. Mr. Aitken can address how E.O. 13422 was developed. He can also offer up OIRA's take regarding how OIRA interprets the new E.O. In testimony before the House Judiciary Committee, he indicated that the view of OIRA was that most of the changes were simply to bring the language of the Executive Order into alignment with practice.

We will also hear from **Professor Peter Strauss** of Columbia Law School and **Dr. Gary Bass** of OMB Watch. They will address some of the institutional challenges OIRA's role pose to the standing of Congress and the dangers that statute may be trumped by non-statutory Presidential guidance. They will also speak to problems of transparency that come with a larger role for Regulatory Policy Officers.

Then **Dr. Robert Hahn** and **Professor Richard Parker** will also testify. Dr. Hahn is famous for studies, done in residence at the American Enterprise Institute, regarding the costs of regulation. His degree is in economics and he has advocated in the past for more reliance on cost-benefit analysis. Professor Parker of the University of Connecticut Law School will offer his insights into the problems with cost-benefit analysis and regulatory budgeting efforts.

Key Issues

Regulatory authority is the main tool Congress has used to charge Executive agencies with responsibilities to protect the environment, public health, the safety of the workplace, the use of public lands and a myriad of other good purposes. Congress obviously cannot pass a law, or amend statute, every time a new threat to air or health arises. Instead, Congress puts into place general purposes, general authority and a set of values that the agency should use in carrying out the law.

When the Office of Information and Regulatory Analysis (OIRA) injects itself into the regulatory process there can be a fine line between guaranteeing that a proposed regulation is convincingly demonstrated and efficient in its likely outcome and substituting the President's values and preferences for the goals and purposes Congress enacted in statute. This line can be crossed either in the guidance to agencies from OIRA or by the way OIRA conducts itself.

OIRA has quietly grown into the most powerful regulatory agency in Washington. The Reagan administration used OIRA to push further and further into the process of vetting regulations. A string of Executive Orders in the 1980s, many issued during David Stockman's tenure at OMB, forced agencies to let OIRA be a full partner—some thought dominant partner—in moving regulations forward. Several House Chairs fought a very bitter struggle to push OIRA back out of the business of interfering with the conduct of agencies as they carried out the law. That fight met only mixed success.

As discussed below, E.O. 12866 was a Clinton-era effort to retain Reagan-initiated White House oversight of agency regulatory processes that had been the product of Reagan initiatives, balanced against the recognition that agencies should have primacy in the regulatory process. The thrust of E.O. 12866 was to pare back the array of regulatory actions that would be swept up into OIRA's review (the estimate was that the annual number of regulations for review declined from 2000 to a mere 500 or so). Clinton's OIRA, while still assertive, was cognizant that it was ultimately the agencies that were charged by Congress with carrying out public purposes and OIRA's assertions of authority had to be tempered by that legal reality.

The Bush Administration has been very aggressive in expanding the role of OIRA. Independent agency action has, in some cases, been by OIRA, which has acted as a very stingy gatekeeper on what proposed regulations can see the light of day. In tone, OIRA has returned to the Reagan-era where OIRA uses its privileged position as "the President's voice" in regulatory matters, to push agencies into rethinking everything they are doing on regulation.

Critics of OIRA's role since 2001 describe a process whereby the values and judgments of OIRA's small staff (dominated by economists) trump the judgments of technical experts in the agencies and supplant the values in statute designed to guide agency regulatory activities. The cumulative effect of OIRA's behavior since 2001 has been to intimidate agencies into running away from pursuing their statutory responsibilities rather than get caught up in the political struggles associated with moving regulation forward. Supporters of this approach are happy to see some office moving to slow agency actions and argue that the net result of OIRA's actions is a more defensible regulation at the end of the day.

How does all this matter for science and the agencies under the Science Committee's jurisdiction?

Every year the Federal Government funds billions of dollars of research at the Environmental Protection Administration, the Department of Labor, the Department of Transportation, the Department of Agriculture, the Department of the Interior, the Department of Energy and the National Oceanic and Atmospheric Administration that contribute directly or indirectly to regulatory considerations. Even the National Institutes of Health and the National Science Foundation fund science that finds its way into regulatory proposals. Experts at agencies—often federal scientists—charged with regulatory responsibilities survey the relevant scientific literature to determine where there may be dangers to the public or the public interest. In determining the need for a regulation, the agency uses science funded with public dollars, as well as that from private sources, to make reasoned assessments of risks and propose responses. This is all to be done consistent with statutory responsibilities as established by Congress.

OIRA has been using its circulars to force agencies to analyze and reanalyze the information underlying and supporting proposed regulations. Now, with the amended Executive Order, OIRA is putting in place an economic criteria—market failure—for regulation and guidance that may have nothing to do with the values established in statute. This effort is coming with no consultation or input from Congress. Further, by making the regulatory policy officer a more empowered gatekeeper, with political allegiance to the President, it raises the chances that the agencies themselves will find it hard during the Bush years to get regulatory proposals started

or completed simply to submit them to OIRA for review. Congress did not empower agencies to protect public health and safety simply to then sit on its hands to see all Congress appropriates for regulatory-relevant science and the legal authority seated in agencies be trumped through a sweeping Executive Order.

Bush Amendments to E.O. 12866

The Bush Administration has amended this Executive Order two times. The first amendment in 2002 simply removed the Vice President from the process, replacing that office with that of the White House chief of staff. This second occasion for amendment has come with limited warning, little discussion and with much broader implications. The attached CRS report goes into detailed discussion of the major changes, and some of their implications. Below is a summary of the key observations.

1. Elevating "Market Failure":

First, the amendment establishes a new standard that must be met by any proposed guidance or regulation. Originally, the first principle guiding submissions to OIRA seeking approval of a proposed regulation was that "[e]ach agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem."

Under the amended language, "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of the problem, to enable assessment of whether any new regulation is warranted."

Critics of OIRA allege that this new standard of "market failure" supplants the values that exist in statute for regulatory action. They also worry that OIRA will use this standard to summarily dispense with proposals that they deem to be unconvincing in their articulation of a market failure. However, there is permissive language allowing for other kinds of analysis. The core question will rest on how OIRA applies this language in practice.

There is a fundamental problem with "market failure": there is no objective test for when market failure is present or when an identified "imperfection" in the operation of a market is sufficient to justify regulatory intervention. Economists offer a model of an ideal, perfect market (perfect information, perfect competition, rational action by all actors, no externalities, no agency problems, predictable transaction costs) and no market in the real world ever works like these theoretical markets. So deciding that a particular "failing" is worthy of intervention is really in the eye of the economist. It is a little like the saying about lawyers: if you don't like the advice yours is giving you, get a new one. The same with economists and market failure.

2. Presidential Appointees as Regulatory Policy Officers

The amendment directs that each agency shall name a regulatory policy officer who shall be a Presidential appointee. While regulatory policy officers had been required in the Executive Order as originally propounded in 1993, the notion that the officer must be a Presidential appointee takes the expert staff of agencies out of the picture. The language of the amendment charges this officer with being "involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order."

This political appointee appears to serve as a kind of gatekeeper's gatekeeper. The officer will compose an annual plan and "no rule-making shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office." Previously such officers were to be involved in the rule-making process and now they have total discretion over the initiation of work that could lead to a regulation. (CRS states that these Regulatory officers are largely drawn from political appointees already so this may not be a notable change; however, the source on that is OIRA and they do not keep a master list of these officers so it is hard to know how to evaluate this assertion.)

Chairman Miller has raised questions about the transparency of activities carried out by the Regulatory Policy Officer. For example, will meetings between the RPO and outside parties on matters that may be considered for guidance or regulation be subject to the same sorts of disclosure that OIRA now routinely makes? Will a decision by an RPO to bar an agency from moving forward with a proposed regulation ever be subject to public disclosure? If a proposal has been drafted and sent

forward to the RPO who sends it back with new guidance, will that exchange be public the way OIRA's response to proposed regulation would be?

Further, we have found in our own survey of agencies, that many agencies have been relying or have now named their General Counsel as RPO. Will the General Counsel make a claim of attorney-client privilege in response to FOIA requests (and even Congressional requests) related to any work on a proposed regulatory action?

3. Aggregate Regulatory Costs and Benefits

The original language of 12866 required a "summary of planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of anticipated costs and benefits." The Bush Administration amendment expands this requirement to direct that each agency provide the "best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities."

Critics allege that this will elevate cost-benefit analysis in the regulatory process. Cost-benefit analysis is a very controversial analytical tool in guiding regulatory behavior. While the call to make sure that the benefits of a regulation exceed its costs has a simple appeal, the reality is that many of the benefits regulations are designed to capture (the survival of a species, to protect the lives and health of citizens, the quality of the air or water) are impossible to accurately value. However, the costs of steps to implement a regulation are usually easy to specify with precision. The result is a process that tends to be very complete in its enumeration of costs and incomplete in its ability to set values on the benefits. Retrospective studies have found that costs used in estimating the costs of a regulation turn out to be overstated. And of course because you are using "dollars" to estimate costs, it provides the illusion of a precision that does not—perhaps cannot—exist.

Critics also view this as a potential first step towards a regulatory "budget" that could be used to stop future regulations based on some "capping" of that budget.

4. Review of Significant Guidance Documents

Under the amendment each agency is to provide OIRA with advance notice of all proposed significant guidance documents. OIRA may then decide which guidance it deems to be "significant" from its perspective and ask for the proposed guidance and a brief explanation of need. "The OIRA administrator shall notify the agency when additional consultation will be required before issuance of the significant guidance document."

There is no time limit on how long OIRA may take in moving on these guidance proposals.

The impact on agency conduct may be very, very significant and could potentially sweep up thousands of such proposals each year. Guidance is issued to communicate to an effected public how an agency intends to interpret or enforce statutory directions. The business community relies on guidance to ensure that conduct will comply with agency intentions for application of law.

Conclusion

While the language of the Amendment to Executive Order 12866 is alarming to many, the fundamental issue is how does OIRA intend to implement it? The reemergence of the "gatekeeper" approach to OIRA under President Bush—an event that has not so far received the kind of institutional push-back from Congress which that role drew in the 1980s—suggests that the rule as amended will be used very aggressively to stall agency action. But how OIRA intends to apply this language in practice is a subject worth some study.

Two other issues loom large from the Committee on Science and Technology's perspective. First, what will these changes imply for the science-based regulatory agencies? Will we increasingly find that the "science" that matters is no longer that of climate, biological or medical researchers, but narrow applications of cost-benefit analysis and market failure theory drawn from economics? Should the Science Committee, uniquely positioned to examine and evaluate research, undertake a more rigorous review of the validity and utility of these economic approaches to regulation?

Second, what does this new amendment imply for the institutional prerogatives of the legislative branch? Agencies exist in statute and are given mandates under the law. Should Congress passively accept an Executive Order that, just as an example, places Presidential appointees in a position where they can arbitrarily block career agency officials from carrying out the purposes of the law Congress charged them with?

The growth of power at the Office of Information and Regulatory Affairs has gone largely unexamined in recent years. This new Executive Order invites Congress as a body, and many, many Committees that are affected, to undertake a vigorous and

thorough review of the changes in that office since 2001. One possible response is to offer legislative language that will enhance the transparency of the actions by Regulatory Policy Officers; that is an option that Chairman Miller is actively considering.

Appendix:

Other Regulatory Tools that OMB has used to Expand its Powers:

Data Quality: There were two recent acts of legislation that affected OMB's oversight of data. They are the Data Access Law and the Data Quality Law. Both of these laws were inserted into omnibus appropriations bills, and neither was fully debated in Congress.

The entire Data Access Law consists of the following short passage:

> "Office of Management and Budget Salaries and Expenses
>
> . . .Provided further, That the Director of OMB amends Section———.36 of OMB Circular A–110 to require federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the *Freedom of Information Act*: Provided further, That if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable use fee equaling the incremental cost of obtaining the data. . ."[11]

The purpose of the law was to increase public access to data conducted with funding from federal grants. Another purpose of the law was to overturn *Forsham v. Harris*,[12] which stood for the principle that data generated by a privately controlled organization which received grant funds from a federal agency were not 'agency records' accessible under the *Freedom of Information Act.*

The *Data Quality Act* ("DQA"), was inserted into the FY 2001 *Consolidated Appropriations Act*.[13] The *Data Quality Act* instructed OMB to establish guidelines to federal agencies for "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by federal agencies." Through its guidelines,[14] OMB directed agencies to establish "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency." To date, there appears to have been over 100 DQA petitions filed with numerous federal agencies. OMB does not compile a list of DQA petitions, so ascertaining the exact number of petitions filed is cumbersome. OMB Watch (*www.ombwatch.org*) keeps track of the individual petitions filed at each agency, and maintains a comprehensive list of DQA petitions.

Two major questions concerning the DQA remain unresolved. The first is whether the DQA applies to agency rule-making. It is clear that the DQA applies to agency action outside the rule-making process (for instance, agency dissemination of information through websites). However, there is no guidance in the actual legislation as to the applicability of the DQA to rule-making. There appears to be a consensus position across the federal agencies that the DQA doesn't apply to rule-making, as the rule-making process already allows for public comment. Furthermore, the DQA contains no reference to the *Administrative Procedure Act.* Nevertheless, industry petitioners have successfully used the DQA petition process to influence agency rule-making. One instance involves the chemical atrizine. As a result of a DQA petition, the EPA included a sentence in a scientific assessment of the risks of atrazine that stated hormone disruption cannot be considered a "legitimate regulatory endpoint at this time."[15] Atrazine is banned in Europe precisely because of the evidence that it is an endocrine disruptor. By attacking the science underlying potential rule-making, the petitioners were able to avoid agency rule-making altogether.

Another major question concerning the DQA is whether DQA petitions are judicially reviewable. Thus far, the major case on the issue held that DQA petitions are not judicially reviewable.[16] However, further challenges in different circuits are planned, and the issue may not be fully settled. Judicial review of DQA petitions would cause massive delays to the petition process.

DQA Based Regulations: OIRA developed two important new regulations based on the *Data Quality Act*: OMB Peer Review Guidelines[17] and OMB Risk Assessment Bulletin (Proposed). OMB's Peer Review Guidelines dictate that "important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government." The guidelines apply to all "scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the Federal Government." OMB's guidelines establish minimum peer review standards for federal agencies. Varying requirements for peer review are established based on the potential influence of the scientific information, with "highly influential scientific assessments" receiving the strictest peer review requirements. OMB asserts its legal authority to impose the

Peer Review Guidelines flows from the *Data Quality Act*'s direction to OMB to provide guidance for federal agencies for "ensuring and maximizing the quality, objectivity, utility and integrity of information" which is disseminated.

OIRA recently proposed a Risk Assessment Bulletin.[18] This has not yet been published in its final form. The Risk Assessment Bulletin establishes "quality standards for risk assessment disseminated by federal agencies." Much like the Peer Review Bulletin, the Risk Assessment guidelines have varying levels of quality standards. There is one set of standards for general risk assessments and another set of stricter standards for influential risk assessments. Influential risk assessment is defined as "a risk assessment the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." OMB again asserts legal authority to issue the bulletin arises from the *Data Quality Act*. This Risk Assessment proposal was soundly rejected by the National Academy of Sciences in their January review. That step seems to have killed the proposal.

Analysis

The effect of the *Data Quality Act*, Peer Review Bulletin and Risk Assessment Bulletin is to impose an additional layer of regulatory administration on agencies that, for the most part, already have strong internal guidelines (at least for peer review and risk assessment). The result of this will likely be greater delay in agency dissemination of information, and a chilling effect that might discourage agencies from attempting to disseminate information in the first place. The bulletins also represent another step in OMB's continuing effort to insert itself into agency affairs. In addition, the possibility remains that OMB will attempt to use its authority under the *Data Quality Act* to insert itself into the agency rule-making process. This could potentially reek havoc on the rule-making process, and create years of new legal challenges related to the rule-making process. Needless to say, that would cause significant slowdown of an already slow rule-making process.

References

[1] 42 Stat. 22, Ch. 18, Sec. 207. OMB currently resides at U.S.C. Title 31, Chapter 5 (31 U.S.C. Sec. 501).

[2] 53 Stat. 1423, Sec. 1.

[3] 84 Stat. 2085, Sec. 102(a), restated 88 Stat. 11, Sec. 1.

[4] 44 U.S.C. Chapter 35, P.L. 96–511, restated P.L. 104–13, 109 Stat. 163.

[5] 44 U.S.C. Sec 3503.

[6] P.L. 104–13, 109 Stat. 163.

[7] P.L. 105–277, 112 Stat 2681.

[8] P.L. 106–554, Sec. 515, 114 Stat. 2763.

[9] 44 U.S.C. Chapter 35, P.L. 96–511, restated P.L. 104–13, 109 Stat. 163.

[10] 44 U.S.C. Chapter 35, P.L. 104–13, 109 Stat. 163.

[11] P.L 105–277, 112 Stat. 2681.

[12] 445 U.S. 169 (1980).

[13] P.L. 106–554, 114 Stat. 2763(A).

[14] 67 FR 8452 (2002).

[15] Data Quality Law is Nemesis of Regulation, *Washington Post,* August 16, 2004.

[16] Salt Institute v. Michael O. Leavitt, 440 F.3d 156 (2006).

[17] 70 FR 2664 (2005).

[18] Notice of proposal at: 71 FR 2600. Text of the proposed bulletin is not published in the *Federal Register*.

[19] P.L. 105–277, 112 Stat. 2681.

[20] P.L. 106–554, Sec. 515, 114 Stat. 2763.

[21] 44 U.S.C. 3502(1).

[22] 67 FR 8460 (2002).

Chairman MILLER. Good morning. This hearing will come to order. Welcome to today's hearing entitled *"Amending Executive Order 12866, Good Governance or Regulatory Usurpation, Part II."* I want to welcome everyone to this hearing today on the role of the Office of Information and Regulatory Affairs, OIRA, in overseeing the development of regulations. The most powerful regulatory office in Washington is the rarely noticed Office of Information and Regulatory Affairs. OIRA was created in the 1980 *Paperwork Reduction Act* with a mandate to reduce the paperwork requirements of the American public. Within a few years of its creation, the Reagan White House had given expansive powers to the office to review all regulatory proposals by federal agencies, and predictably, an office supposedly created to reduce paperwork put standards and procedures in place that required agencies to generate mountains of paper. Congress and the White House struggled over the proper role of OIRA all through the 1980s. Various Congressional committees believe that OIRA prevented agencies from complying with statutory requirements to clean up the environment, to protect the public and to make workplaces safer.

The Clinton Administration's Executive Order 12866 resolved some of the same aspects of that fight. This subcommittee took testimony from a former director of OIRA, Sally Katzen, in February. Ms. Katzen was the principal author of Executive Order 12866. She testified that the Clinton Administration order assured that agencies carried more influence over the substance of the regulation than did OIRA. OIRA could ask hard questions, ask for more data or more clarity, but in the end, statutory authority and expertise was with the agency and OIRA must respect that.

Executive Order 13422 is a new chapter in OIRA's role and opens again some of the issues that were resolved in the Clinton Administration order. Under this order, not just major regulations but guidance is subject to review by OIRA and the order creates a new requirement, and I understand, Mr. Aitken, you will testify today it is not really new but it creates a new requirement, market failure, for any agency to promulgate any regulation. Market failure does not appear in any statute as a consideration of rule-making and in fact Congress flatly rejected that argument, that the market will work things out. Given time, if we leave it alone, the market will work it out. Congress flatly rejected that argument by enacting legislation that granted rule-making authority. The order also requires agencies to compose annual summaries of the cumulative costs of proposed regulations, another requirement for rulemaking that does not appear in statute, and the order creates within each agency a regulatory policy officer who can smother regulatory efforts in the crib before an agency can even begin considering a regulatory action. The cumulative effect of all these changes is to seize for the President and OIRA power over regulatory efforts consistent neither with statute nor the Constitution. Professor Strauss has it just right when he warns us that there are many potential hazards on this path.

I want to hear what process was followed in developing this new executive order, what deficiencies in the Clinton Administration Executive Order 12866 this new order is designed to address, and how OIRA intends to apply the various new requirements. I want

to also hear the advantages and pitfalls of using cost-benefit analysis, market failure and even a regulatory budget as a tool for regulatory policy. The power given to regulatory policy officers is especially troubling. RPOs are presidential appointees with political ties. OIRA speaks for the President and OIRA has set out an economic standard as a guide to regulatory proposals, a standard unsupported by statute. RPOs will address that standard while also serving in agencies that have a statutory obligation that is entirely different from the values and preferences of OIRA, or at least may be. Unlike the Clinton Administration, Executive Order 13422 requires no disclosure. There are no transparency requirements to explain the actions of RPOs. Mr. Aitken, in your testimony today, you will sing the praises of transparency but I think there are questions about how the RPO's role is consistent with expectations of transparency in government. Will we ever know in a pre-rule period what has happened, who has spoken with him, how language has been changed in an proposal or what proposed rules were stopped in their tracks by an agency's RPO? What sort of discussions may occur between OIRA and the RPO regarding OIRA's expectations, and how would the Congress, much less the public, ever learn that those exchanges had occurred? Deciding issues that affect the lives of millions of Americans in secret is incompatible with our democratic traditions.

[The prepared statement of Chairman Miller follows:]

PREPARED STATEMENT OF CHAIRMAN BRAD MILLER

Good morning, I want to welcome everyone to Part II of our hearing on role of the Office of Information and Regulatory Affairs in overseeing the development of regulations.

The most powerful regulatory office in Washington is the rarely noticed Office of Information and Regulatory Affairs (OIRA). OIRA was created in the 1980 Paperwork Reduction Act with a mandate to reduce the paperwork requirements on the American public. Within a few years of its creation, the Reagan White House had given expansive powers to that office to review all regulatory proposals by federal agencies. Predictably, an office supposedly created to reduce paperwork put standards and procedures in place that required agencies to generate mountains of paper.

Congress and the White House struggled over the proper role of OIRA all through the 1980s. Various Congressional Committees believed that OIRA prevented agencies from complying with statutory requirements to clean up the environment, protect the public and make workplaces safer.

The Clinton Administration's Executive Order 12866 resolved some of the aspects of that fight. This Subcommittee took testimony from a former director of OIRA, Sally Katzen, in February. Ms. Katzen was the principle author of E.O. 12866. She testified that the Clinton Administration Order assured that agencies carried more influence over the substance of a regulation than did OIRA. OIRA could ask hard questions, ask for more data or more clarity, but in the end statutory authority and expertise reside in the agencies and OIRA must respect that.

Executive Order 13422 is a new chapter in OIRA's role. Under this order, not just major regulations, but guidance is subject to review by OIRA. And the order creates a new requirement—"market failure"—for any agency to promulgate any regulation. "Market failure" does not appear in any statute as a consideration in rule-making; in fact, Congress flatly rejected the argument that the market will solve the problem when Congress enacted the legislation granting rule-making authority.

The Order also requires agencies to compose annual summaries of the cumulative costs of proposed regulations, another requirement for rule-making that does not appear in statute. And the Order creates within each agency a "Regulatory Policy Officer" who can smother regulatory efforts in the crib before an agency can even begin considering a regulatory action. The cumulative effect of all these changes is to seize for the President and OIRA power over regulatory efforts consistent neither with statute nor with the Constitution.

Professor Strauss has it just right when he warns us that there are many potential hazards on this path.

I want to hear what process was followed in developing this new Executive Order, what deficiencies in E.O. 12866 is this designed to redress, and how OIRA intends to apply these new requirements.

I want to hear the advantages, and pitfalls, of using cost benefit analysis, market failure and even a regulatory budget as a tool for regulatory policy.

The power give to Regulatory Policy Officers is especially troubling. RPOs are Presidential appointees with political ties. OIRA speaks for the President and OIRA has set out an economic standard as a guide to regulatory proposals, a standard unsupported by statute. RPOs will apply that standard while also serving in agencies that have statutory obligations that are entirely different from the values and preferences of OIRA?

Unlike the Clinton Administration order, Executive Order 13422 requires no disclosure requirements to actions by RPOs? Will we ever know, in that pre-rule period, what has happened, who has spoken with whom and how language may be changed in a proposal, or what proposed rules were stopped in their tracks buy an agency's RPO? What sort of discussions may occur between OIRA and the RPO regarding OIRA's expectations and how would the Congress, much less the public, ever learn that those exchanges had occurred.

Deciding issues that affect the lives of millions of Americans in secret is incompatible with our democratic traditions.

Chairman MILLER. With that, I recognize my Ranking Member today, Mr. Sensenbrenner, for five minutes.

Mr. ROHRABACHER. Yes, sir. As you can see, Sensenbrenner and Rohrabacher look a little bit alike there.

Chairman MILLER. This fellow here.

Mr. ROHRABACHER. Okay. You won't try to pronounce Rohrabacher, and I fully understand that.

Chairman MILLER. The gentleman from California.

Mr. ROHRABACHER. Well, I would say that it is a pleasure to be with you today but I actually am taking the spot of Mr. Sensenbrenner, who was called away because he is serving as Ranking Member on the new Select Committee on Energy Independence and Climate Change, so I am taking his spot while he is out doing some other things that are equally important.

I would like to welcome the witnesses and I understand that many of them actually testified before Congress on this topic before this, some of them having testified before the Judiciary Committee in February. I am also glad to see that the Administration is here to clear up any misconception either side of the aisle may have about some of the proposals that have been made by the Administration.

I served on the Science Committee for 20 years so I am fully aware of how science and research influence the regulatory process. I have also seen how several administrations have chosen to organize and oversee the regulatory process. In the past each president has set up his own guidelines when taking office. With that in mind, I think it is worth nothing that we are here today discussing this issue in the seventh year of the current Administration. Up until this point, the current Administration has been operating under President Clinton's executive order. Furthermore, the new executive order that we are looking at today simply makes minor clarifications and leaves the vast majority of the Clinton Administration's executive order in place, asking agencies to report work on market failure and cost-benefit analysis. Well, they are already required to do this. It doesn't seem like a great leap in a new direction to me. Also, if we are going to have a regulatory policy and

if we are going to have officers of these agencies who are making decisions, which is what the previous executive orders have required, it might be a good idea to ensure that they are accountable to someone. Ultimately, all executive orders only stand as long as the current president is in office. Thus, the voters will have a way to determine who they should elect as president of the United States and who they will reelect based on the executive orders that come out of the various candidates. In all likelihood, the next president will modify or even replace the particular executive orders that we are talking about within a very short period of time, within just a few years, or even a short period of time after the next election, so just a very short period of time from now.

Viewing this topic in this light, I think that the issues that we will address here today have less to do with their policy implications and more to do with who issued these policies. That being said, I will certainly follow how this executive order is implemented to ensure that public health and safety are observed and that there continues to be a transparency and accountability in our regulatory process, and again, let me note this. When President Clinton became president, I was fortunate enough to be serving in Congress at that time, the first thing he did was eliminate every U.S. attorney, fire every U.S. attorney without explanation, simply firing them, and there has been a big brouhaha about President Bush getting rid of several U.S. attorneys, but unfortunately, Mr. Gonzales felt compelled to offer some explanation, which now has put him into hot water. President Clinton chose not to offer any explanations of that. Well, here we are in a similar situation where President Clinton offered executive orders, this is his right to do so, and this President seven years into his Administration now is altering something that President Clinton did immediately upon entering his term of office and there is now an attempt to call this into question, and I would just guess that if it was any other president or the past president was doing this, this would not be an issue because the President has a right to issue executive orders.

With that said, I am looking forward to hearing from the witnesses.

[The statement of Mr. Rohrabacher follows:]

PREPARED STATEMENT OF REPRESENTATIVE DANA ROHRABACHER

Thank you Mr. Chairman. I will be filling in for Mr. Sensenbrenner today, as he was called away to serve as Ranking Member on the Select Committee on Energy Independence and Climate Change.

I'd like to welcome our witnesses here today. I understand that, for many of them, this is their second appearance before Congress on this topic—having testified before the Judiciary Committee in February. I'm also glad to see that the Administration is here to clear up any misconceptions either side of the aisle may have.

I've served on the Science Committee for almost 20 years, so I am fully aware of how science and research influence the regulatory process. I've also seen how several Administrations have chosen to organize and oversee the regulatory process. In the past, each President has set up his own guidelines upon taking office. With that in mind, I think it's worth noting that we are here today discussing this issue in the seventh year of the current Administration. Up until this point, the current Administration had been operating under President Clinton's Executive Order. Furthermore, the new Executive Order that we are looking into today simply makes minor clarifications and leaves the vast majority of the Clinton Administration's Executive Order in place. Asking Agencies to report work on "market failure" and "cost-benefit analysis" that they are already required to do doesn't seem like a giant leap to me. Also, if we are going to have regulatory policy officers at agencies as

the previous Executive Order required, it might be a good idea to ensure that they are accountable to someone.

Ultimately all Executive Orders only stand as long as the current President is in office. In all likelihood, the next President will modify, or even replace this Executive Order in a few years. Viewing this topic in this light, I think that the issues that we will address here today have less to do with their policy implications, and more to do with who issued them. That being said, I will certainly follow how this Executive Order is implemented to ensure that public health and safety are preserved, and that there continues to be transparency and accountability in our regulatory process.

Chairman MILLER. Thank you. There are no other Members here, but if any other Members of the Committee wish to present opening statements for the record, we can receive them in writing and include those.

[The prepared statement of Mr. Costello follows:]

PREPARED STATEMENT OF REPRESENTATIVE JERRY F. COSTELLO

Good Morning. Thank you Mr. Chairman for calling a second hearing to examine the President's recent amendment to Executive Order 12866, which requires Federal Government agencies to submit any proposed regulations to the Office of Management and Budget (OMB) for pre-approval. On Tuesday, February 13, 2007, the Subcommittee held its first hearing on Executive Order 12866. The February hearing provided significant testimony highlighting several issues worthy of further work and oversight.

Regulatory authority is the main tool Congress has used to charge Executive agencies with responsibilities to protect the environment, public health, safety in of the workplace, the use of public lands and a number of other good purposes. I have concerns that the amendment put in place by the Bush Administration goes one step further than the current process by requiring agencies to identify in writing the specific market failure or problem that warrants the proposed regulation or guidance.

I look forward to hearing the perspective of the witnesses on how the Executive Order developed and what are the consequences of changes to the language to Executive Order 12866.

I welcome today's witnesses and look forward to their testimony.

Chairman MILLER. Mr. Aitken, with that bit of advice, support openness, transparency and accountability but don't explain yourself or you will get in trouble. We welcome your testimony today. Steve Aitken is the general counsel for the Office of Information and Regulatory Affairs, OIRA, the Office of Management and Budget, and for the last ten months Mr. Aitken has served as the acting administrator of OIRA. Mr. Aitken, your oral testimony is limited to five minutes but your entire written testimony will be placed in the record, and after you have given your testimony, the Members of the Committee will have five minutes each to ask questions. We do swear our witnesses. Mr. Aitken, do you have any objection to being sworn in? Okay. You also have a right to be represented by counsel. Do you have counsel here today?

Mr. AITKEN. No.

Chairman MILLER. These questions are designed to put you at ease. Please stand and raise your right hand.

[Witness sworn]

Mr. ROHRABACHER. Would we note for the record that the people on this side of the hearing are never sworn in that way?

Panel 1

TESTIMONY OF MR. STEVEN D. AITKEN, GENERAL COUNSEL FOR THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET

Mr. AITKEN. Thank you, Mr. Chairman. Chairman Miller, Representative Rohrabacher and distinguished Members of the Subcommittee, thank you for giving me the opportunity today to testify before you on Executive Order 13422.

I am Steven Aitken. For a ten-month period starting in June of last year and ending at the beginning of this month, I served as Acting Administrator of the Office of Information and Regulatory Affairs. I have worked at OMB for nearly 18 years. Except for my service as OIRA's Acting Administrator, I have served in the Office of the General Counsel at OMB, first as an Assistant General Counsel and then as a Deputy General Counsel. I am testifying today in my capacity as the former Acting Administrator of OIRA.

Earlier this year the President issued Executive Order 13422, which made several amendments to Executive Order 12866. The most important of these amendments relate not to the regulations that federal agencies develop but rather to the guidance that federal agencies develop. In addition, on that same day the OMB director issued the Bulletin on Agency Good Guidance Practices. This is the final version of the bulletin that OMB issued in proposed form for public comment in November of 2005. As I note in my written testimony, the draft bulletin received support from a broad and diverse range of commenters and the bulletin reflects good guidance principles that are found in the FDA's Good Guidance Regulations and that have been supported by the Administrative Conference of the United States and by the American Bar Association.

The Bulletin and Executive Order share a good government goal, to improve the way that the Federal Government does business by increasing the quality, accountability and transparency of agency guidance documents including the opportunity for the public to review and comment on guidance. The good government improvements that are made by the bulletin are reinforced by the recent order which provides for a relatively informal process whereby some but by no means all of the significant guidance documents that are developed by agencies will be submitted to OMB for interagency review. In addition, the recent order makes several additional good government improvements. There has been some confusion in the press and elsewhere about these changes and I would like to address those.

First, concerns have been raised about the order's provisions regarding regulatory policy officers. First, these officers are not new. When President Clinton issued Executive Order 12866, he directed each agency head to designate a regulatory policy officer. In addition, while the recent order specifies that these regulatory policy officers will be presidential appointees, the case is that for most departments and major regulatory agencies, they already were presidential appointees subject to Senate confirmation.

In addition, concerns have been expressed regarding the recent order's discussion of market failure. Before explaining what this

amendment does do, I want to explain first what it does not do. First, the concept of market failure is not new to Executive Order 12866. Instead, it has been an integral part of that order since President Clinton issued it in 1993. In the order, as issued by President Clinton, the President referred not once but twice to the "failures of private market" as a justification for regulation. That is the same thing as a market failure. Second, the recent order does not make a market failure the only basis on which an agency can justify regulatory action. Instead, the order expressly allows an agency to identify as a justification for regulatory action any other significant problem that the agency intends to address. That is what the recent order does not do. What it does do is include in Executive Order 12866 references to three classic examples of market failure, namely externalities, market power and lack of information. These three examples are not new to the implementation of Executive Order 12866. In fact, in 1996 then-OIRA administrator Sally Katzen issued Best Practice Guidelines to the agencies that included a separate discussion of market failure, and those guidelines discussed these three classic examples of market failure.

Some have expressed concern that the recent order could prevent agencies from issuing regulations to protect public health and safety but this is not correct. Many of the most significant regulations that agencies issue are in fact in response to market failures. For example, environmental pollution is the classic example of an externality market failure. Another type of market failure stems from a lack of information. In response to this kind of market failure, the Food and Drug Administration issued a regulation that requires nutritional labels on packaged foods to display the amount of trans fats in them. This rule was not driven by a specific statutory mandate but by the market failure of lack of information.

Finally, I would like to mention that late yesterday the OMB director and the OIRA administrator finalized a memorandum to agencies that provides them with questions and answers to assist them in the implementation of the recent order and bulletin. A copy of the memorandum was forwarded to the Subcommittee late yesterday and it is being posted on OMB's web site this morning.

This concludes my opening statement. I would welcome any questions that the Subcommittee has.

[The prepared statement of Mr. Aitken follows:]

PREPARED STATEMENT OF STEVEN D. AITKEN

Chairman Miller, Ranking Member Sensenbrenner, and distinguished Members of this subcommittee, thank you for inviting me to this hearing and for giving me the opportunity to testify before you today on Executive Order 13422, in which the President amended Executive Order 12866.

I am Steven D. Aitken. For a ten-month period, starting in June of last year and continuing into the first week of this month, I served as the Acting Administrator of the Office of Information and Regulatory Affairs (OIRA), an office within the Office of Management and Budget (OMB). I have worked at OMB for nearly 18 years. Except for my service as OIRA's Acting Administrator, I have served in the Office of General Counsel at OMB, first as an Assistant General Counsel and then as Deputy General Counsel. I am testifying today solely and exclusively in my capacity as the former Acting Administrator of OIRA.

On January 18th, the President issued Executive Order 13422, which made several amendments to Executive Order 12866 on "Regulatory Planning and Review." The most important of these amendments relate, not to the regulations that federal agencies develop, but rather to the guidance that federal agencies develop and pro-

vide to the public. In addition, also on January 18th, the OMB Director issued the OMB Bulletin for Agency Good Guidance Practices. This is the final version of the bulletin that OMB issued in proposed form for public comment in November 2005.[1]

The Executive Order and Bulletin share a common goal: namely, the good-government objective of improving the way that the Federal Government does business—by increasing the quality, public participation, and accountability of agency guidance documents and their development and use. Moreover, the Bulletin and the new Executive Order will operate in a complementary fashion to improve agency guidance documents.

For this reason, in order to explain the Executive Order's guidance provision, it is first necessary for me to outline briefly the common background for both the Bulletin and the Executive Order and then to explain, again briefly, how the Bulletin is designed to improve the way that agency guidance documents are developed, issued and used. I will then provide a description and explanation of the Executive Order's guidance provision.

Following that, I will discuss and explain the recent Executive Order's other *non*-guidance provisions. Among the provisions that I will address are the Executive Order's provisions regarding Regulatory Policy Officers, market failures, and formal rule-makings. As part of my discussion of these provisions, I will seek to correct the misunderstandings that have arisen regarding them.

Background on the Good Guidance Provisions of the Bulletin and Executive Order[2]

As OMB has previously stated, agency guidance documents can have "enormous value."[3] As OMB explained in 2002: "As the scope and complexity of regulation and the problems it addresses have grown, so too has the need for government agencies to inform the public and provide direction to their staffs. To meet these challenges, agencies have relied increasingly on issuing guidance documents."[4] Guidance documents are issued by agencies throughout the Federal Government, and they address the wide range of societal activities that are affected, in one way or the other, by the Federal Government and its programs. Thus, it is not surprising that, depending on the situation, agency guidance can be addressed to individuals, businesses (both small and large), organizations, State, local, and tribal governments, and others.

For instance, guidance can take the form of an agency explaining to members of the public how they can participate in a federal program. An example of this kind of guidance is the *Medicare and You* handbook that the Centers for Medicare and Medicaid Services (CMS) distribute to Medicare beneficiaries annually.

Guidance can also take the form of an agency providing advice and assistance to members of the public about recommended actions to ensure that they are in compliance with federal laws and regulations. In addition to providing advice and assistance to the regulated community on how to comply with the agency's regulations, such guidance also furthers consistency and fairness in an agency's enforcement of its regulations.[5] Depending on the context, the audience for this guidance can include individuals, small entities (such as small businesses and organizations, as well as local governments), large corporations, and/or State governments.

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[1] Executive Order 13422 and the Final Bulletin are published in the *Federal Register* at, respectively, 72 FR 2763 (January 23, 2007), and 72 FR 3432 (January 25, 2007). OMB requested public comment on the proposed bulletin at 70 FR 71866 (November 30, 2005), and extended the comment period at 70 FR 76333 (December 23, 2005). These documents, along with the public comments that OMB received on the proposal and the OMB Director's memorandum issuing the Bulletin (Memorandum M–07–07), are available on OMB's website. The original version of Executive Order 12866, issued in 1993, was published in the *Federal Register* at 58 FR 51735 (October 4, 1993). Executive Order 12866 was previously amended once, in 2002, by Executive Order 13258, which was published in the *Federal Register* at 67 FR 9385 (February 26, 2002).

[2] I discussed this background in greater depth in my testimony of February 13, 2007, before the Subcommittee on Commercial and Administrative Law of the House Committee on the Judiciary. That testimony is available on OMB's website at *http://www.whitehouse.gov/omb/legislative/testimony/oira/aitken_02132007.pdf.*

[3] Office of Management and Budget, *Stimulating Smarter Regulation: 2002 Report to Congress on the Costs and Benefits of Federal Regulations* (2002), p. 72.

[4] Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, 67 FR 15014, 15034 (March 28, 2002).

[5] "Guidance documents, used properly, can channel the discretion of agency employees, increase efficiency by simplifying and expediting agency enforcement efforts, and enhance fairness by providing the public clear notice of the line between permissible and impermissible conduct while ensuring equal treatment of similarly situated parties." Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, *id.*, 67 FR at 15034.

Examples of this type of guidance are the compliance-assistance guides that federal agencies prepare and make available to small businesses. Congress has required federal agencies to prepare and issue such guidance in the *Small Business Regulatory Enforcement Fairness Act of 1996*.[6] In addition, Congress in the *Small Business Paperwork Relief Act of 2002*[7] assigned to OMB the responsibility, which is carried out by OIRA, of publishing annually in the *Federal Register* a notice that refers small businesses to the Internet site where they can locate the compliance assistance resources that federal agencies have prepared for their use.[8]

In sum, agency guidance documents are intended to—and do—have an impact on society. Depending on the situation, this impact can be relatively small or can be very substantial. As a result, while it is the case that guidance documents (unlike regulations) are not legally binding on the public, agency guidance documents nevertheless can potentially have an impact on society that is of comparable magnitude to the impact that regulations have on society.

In recognition of the impact that its guidance has on society, the Food and Drug Administration (FDA) in February 1997 issued a "Good Guidance Practices" document to govern how the FDA develops, issues, and uses its own guidance documents.[9] Later that year, and building on this FDA policy, Congress in the *Food and Drug Administration Modernization Act of 1997*[10] directed the FDA to issue a regulation by 2000 "specifying the policies and procedures of the [FDA] for the development, issuance, and use of guidance documents."[11] Following this directive, FDA in early 2000 issued for public comment a proposed rule on Good Guidance Practices.[12] After it reviewed and considered the public comments, FDA finalized the rule later that year.[13]

The FDA's Good Guidance Practices regulation is found at 21 C.F.R. § 10.115. Following the congressional direction in the 1997 Act, the FDA regulation provides that FDA, among other things, shall seek public comment on its guidance documents, either before or after their issuance (depending on their level of significance) and consider the comments[14]; shall make its guidance documents easily available to the public by posting it on the Internet[15]; "must not include [in its guidance documents] mandatory language such as 'shall,' 'must,' 'required,' or 'requirement,' unless FDA is using these words to describe a statutory or regulatory requirement"[16]; "must have written procedures" in each FDA center and office "for the approval of guidance documents," which procedures "must ensure that issuance of all documents is approved by appropriate senior FDA officials"[17]; and must provide members of the public with an opportunity to submit and seek resolution of a complaint "that someone at FDA did not follow the requirements in [the regulation] or. . .treated a guidance document as a binding requirement."[18] These FDA regulations went into effect in October 2000, and therefore have now been in operation for six years.

In sum, as I have just outlined, the Congress and the FDA both recognized that, because of the impact that FDA's guidance can have on society, it was important that FDA's guidance be subject to public comment (before or after its issuance); be readily available to the public; be developed through agency procedures that ensure the review and approval of appropriate agency officials before it is issued; be followed in practice by agency employees; and avoid the inclusion of language that would suggest to the public that the document is mandatory rather than what it actually is—namely, guidance. It should also be noted that these requirements, in

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[6] P.L. 104–121, Title II, Subtitle A; 5 U.S.C. § 601 note.

[7] P.L. 107–198, Section 2(a); 44 U.S.C. § 3504(c)(6).

[8] OIRA published the 2006 notice last summer, in which OIRA explained that small businesses can go to one Internet address (*www.business.gov/sbpra*) and find the compliance-assistance resources that are available from the 15 Cabinet Departments and 25 other federal agencies. *See* 71 FR 39691 (July 13, 2006).

[9] 62 FR 8961 (February 27, 1997).

[10] P.L. 105–115, § 405; 21 U.S.C. § 371(h).

[11] *Id.* § 371(h)(5).

[12] 65 FR 7321 (February 14, 2000) (proposed rule).

[13] 65 FR 56468 (September 19, 2000) (final rule).

[14] 21 C.F.R. § 10.115(g).

[15] *Id.* This direction is consistent with the 2001 recommendation by the American Bar Association. 3 American Bar Association, "Recommendation on Federal Agency Web Pages" (August 2001) (agencies should maximize the availability and search ability of existing law and policy on their websites and include their governing statutes, rules and regulations, and all important policies, interpretations, and other like matters on which members of the public are likely to request).

[16] *Id.* § 10.115(i)(2).

[17] *Id.* § 10.115(j).

[18] *Id.* § 10.115(o).

particular the requirements for internal-agency review and approval and for public comment, help to ensure that guidance documents are of high quality.

The FDA Good Guidance Practices regulation also addresses concerns that courts have raised about the improper development and use of agency guidance documents. In its 2000 decision in the *Appalachian Power* case, the United States Court of Appeals for the District of Columbia Circuit discussed these concerns:

> "The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the *Federal Register* or the *Code of Federal Regulations*."

Appalachian Power Co. v. EPA, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (striking down emissions monitoring guidance as legislative rule requiring notice and comment).[19]

OMB's Issuance of the Proposed and Final Bulletin:

OMB believes that federal agency guidance should be developed, issued and used through an agency's adherence to procedures that ensure quality, transparency, public participation, coordination, and accountability. For this reason, OMB developed (in consultation with federal agencies) a draft OMB Bulletin that would establish as government-wide policy a set of "best practices" for achieving these goals.

As I earlier noted, OMB then sought public comment on this draft bulletin by issuing it in November 2005 as a proposal for public comment.[20] OMB received 31 public comments on the proposal, and these comments are available on OMB's website. These comments were largely positive, and reflected the diverse nature of federal guidance documents and the groups in American society that are affected by them. Below are examples of some of the associations that submitted comments (as noted below, these listed associations supported OMB's development of a bulletin on Good Guidance Practices, while also providing their suggestions for how OMB could improve the bulletin):

— **the Association of American Medical Colleges,** representing all 125 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and 94 academic and scientific societies ("The AAMC commends the OMB for its proposal to establish consistent and appropriate standards for developing good guidance practices within federal agencies.");

— **the National Association of Home Builders,** representing more than 220,000 members involved in home building, remodeling. multifamily construction, property management, subcontracting, design, housing finance, building product manufacturing and other aspects of residential and light commercial construction ("The National Association of Home Builders (NAHB) would like to thank the Office of Management and Budget (OMB) for proposing a process to bring transparency and consistency to Executive Branch activities that affect the public directly, but do not qualify as rules under the Administrative Procedure Act (APA).");

— **the American Society of Safety Engineers,** representing 30,000 members ("ASSE commends OMB/OIRA for taking a proactive stance to ensure that agencies can readily provide interpretation and guidance of regulations, but still do so in a manner that affords due process to the regulated community and that is in accordance with the requisites of the *Administrative Procedure Act*, 5 USC 551 et seq.");

— **the National Funeral Directors Association,** representing more than 11,000 funeral homes in all 50 states ("NFDA supports the Office of Management and Budget (OMB) proposal to establish standards to increase the

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[19] *See also Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as legislative rule requiring notice and comment); *Chamber of Commerce v. Dept. of Labor*, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as legislative rule requiring notice and comment).

[20] 70 FR 71866 (November 30, 2005).

quality and transparency of agency guidance practices and the guidance documents produced through them.");

— **the Association of Metropolitan Planning Organizations** ("In general, AMPO strongly supports the Proposed Bulletin's intent and reliance on the guidance practices adopted by the Food & Drug Administration ('FDA') at 21 C.F.R. 5 10.115.");

— **the Ornithological Council,** which consists of eleven leading scientific ornithological societies—the American Ornithologists' Union, Association of Field Ornithologists, CIPAMEX, Cooper Ornithological Society, Neotropical Ornithological Society, Pacific Seabird Group, Raptor Research Foundation, Society of Canadian Ornithologists/La Société des Ornithologistes du Canada, Society for Caribbean Ornithology, Waterbird Society, and Wilson Ornithological Society—that together have a membership of nearly 6,500 ornithologists ("we would like to express our gratitude to OIRA for its efforts to improve agency guidance practices");

— **the Aircraft Owners and Pilots Association,** representing over 407,000 members ("AOPA shares OMB's concern that agency guidance practices should be more transparent, consistent and accountable. We also agree with OMB that the absence of procedural review mechanisms undermines the lawfulness, quality, fairness and accountability of agency policy-making.");

— **the National Leased Housing Association,** which represents the interests of housing agencies, developers, lenders, housing managers and others in providing federally assisted rental housing, and whose members are primarily involved in the Section 8 housing programs and are involved with the operation of rental housing for over three million families ("we commend OMB for its efforts");

— **the American Road and Transportation Builders Association,** whose membership includes public agencies and private firms and organizations that own, plan, design, supply and construct transportation projects throughout the country ("Once again, ARTBA is extremely supportive of the GGP and feels that it represents a significant step forward in the regulatory process. It will engender fairness and improved dialogue between agencies and those that have a vital stake in the guidance they issue. ARTBA and our members are eager to take advantage of the new opportunities for involvement in the guidance process offered by the GGP and help OMB make the GGP standard agency practice."); and

— **the Associated Equipment Distributors,** representing 1,200 construction equipment distributors, manufacturers and industry-service firms (" Our association thanks the Office of Management and Budget (OMB) for recognizing the impact that guidance material issued by federal regulatory agencies has on the regulated community. We agree with the OMB that transparency in the guidance drafting process is critical, as guidance should not be used for rule-making.").

As I have indicated, the comment letters from these associations can be found on OMB's website, along with the other comment letters on the proposed bulletin.[21]

On January 18th of this year, after considering the public comments and after further consultation with federal agencies, the OMB Director issued the Final Bulletin on Agency Good Guidance Practices.[22] The final version of the Bulletin is very similar to the proposal in its overall framework, but—as OMB explained in the preamble to the final Bulletin—OMB made a number of improvements to the Bulletin in response to comments that we received from the public and during the interagency review process.

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[21] OMB also received comments, some supporting and others opposing the proposed bulletin, from the following (in alphabetical order): the Aeronautical Repair Station Association, the American Bar Association, the American Chemistry Council, the American Composites Manufacturers Association, the American Petroleum Institute, AMGEN, C. Blake McDowell (Professor of Law), Citizens for Sensible Safeguards (OMB Watch), Coalition for Effective Environmental Information, Consumer Specialty Products Association, General Electric Company, Keller and Heckman LLP, McKenna Long & Aldridge LLP, Mercatus Center, National Mining Association, Natural Resources Defense Council, PIMA County (AZ) Wastewater Management Department, Regulatory Checkbook, Sanofi-aventis, Stuart Shapiro Ph.D. (Edward J. Bloustein School of Planning and Public Policy, Rutgers University), U.S. Chamber of Commerce.

[22] OMB Memorandum M–07–07 (January 18, 2007), which is found on OMB's website. The final Bulletin is published in the *Federal Register* at 72 FR 3432 (January 25, 2007).

The following are a few of the noteworthy provisions of the Bulletin, which reflect the requirements of the FDA's Good Guidance Practices regulation and are designed to improve the quality, transparency, public participation, and accountability of agency guidance documents:

- Each agency will ensure (as agencies should be doing anyway, as a matter of good internal management) that appropriate officials within the agency have reviewed and approved the agency's issuance of "significant" guidance documents;
- Agencies will maintain on their websites current lists of their "significant" guidance documents that are in effect, so that the public can know what guidance applies to them;
- Agencies will provide the public with access to and the opportunity to provide feedback on their "significant" guidance documents. Agencies will advertise on their websites a means for the public to submit comments electronically on these guidance documents; and
- For those guidance documents that are "economically significant" (e.g., a guidance document that "may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more"), agencies will publish drafts of the documents in the *Federal Register,* invite public comment on them, and prepare responses to the comments before finalizing the guidance.

In recognition of the potentially broad range of guidance documents that are issued by federal agencies, the Bulletin also (1) includes certain express exclusions from the definition of "significant" and "economically significant" guidance document; (2) authorizes OMB to exempt "economically significant documents" (singly or by category) from the requirement for *prior* public comment before issuance; and (3) includes an express exception from the Bulletin's requirements for "emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow."

In light of concerns that have been raised about the final Bulletin and the Executive Order, this last point bears emphasis. The Bulletin does *not* stand in the way of a federal agency responding appropriately to an emergency situation. In addition, the Bulletin does not override a federal agency's obligation to comply with applicable laws.

Executive Order 13422

The Executive Order's Guidance Provision

In the furtherance of its goal to improve the guidance documents that federal agencies develop and issue, the Bulletin is reinforced by the principal provision in Executive Order 13422, which the President issued, also on January 18th. Through an amendment to Executive Order 12866, which President Clinton issued in 1993, the recent executive order provides for a relatively informal process whereby federal agencies will submit to OMB, for interagency review, *some*—but by *no* means all—of the "significant guidance documents" that they develop.

It is important to underscore the point that this amendment provides for an *opportunity* for interagency review, and therefore that guidance documents are *not* treated the same as regulations. When he issued Executive Order 12866 in 1993, President Clinton directed agencies to submit the drafts of all of their "significant" regulations to OIRA for review (subject to certain limited exceptions). By contrast, agencies are *not* required under the recent amendments to submit all of their "significant" guidance documents to OMB for review. Instead, the recent executive order requires agencies to *inform* OMB of upcoming significant guidance documents, which thereby provides an *opportunity* for interagency review to occur.

In this regard, just as the new Bulletin directs agencies to follow good guidance practices that, to a greater or lesser extent, are probably being followed by many agencies for many of their guidance documents (e.g., posting them on the agency's website), the recent Executive Order—in recognizing the desirability of ensuring an *opportunity* for interagency review—also reflects a practice that already happens in a number of situations.

In other words, interagency review of important guidance documents is *not* new. And, one reason why such review is desirable, and already happens, is because the programs and activities of one federal agency often overlap or have implications for the programs and activities of one or more other federal agencies. For example, in June of last year, the Department of Health and Human Services (HHS) issued a State Medicaid Director letter that provides guidance on the implementation of the provision in the *Deficit Reduction Act of 2005* that requires individuals claiming U.S. citizenship to provide—when initially applying for Medicaid or upon the first

redetermination—satisfactory documentary evidence of citizenship or nationality. Before HHS finalized and issued this guidance, OMB ensured that HHS consulted first with affected and interested agencies—the Departments of State and Homeland Security, and the Social Security Administration. This interagency consultation, which took place in a two-week period, ensured that HHS had the benefit of the expertise and experience of these other agencies and that the HHS guidance took into account their interests and programs.

This *interagency* coordination, then, had the effect of improving the quality of the HHS guidance in the same way that the quality of guidance can be improved through *public participation* and *internal-agency review and approval.*[23] Thus, by ensuring that there is an *opportunity* for interagency review, this amendment made by Executive Order 13422 serves as a complement to the requirements in the OMB Bulletin for public participation and internal-agency review and approval.

In addition, as OMB explained in March 2002, interagency review of a guidance document is also justified because "interagency review can ensure that agency action is consistent with Administration policy and is beneficial from a broader, societal perspective."[24] This type of review during the development of agency *guidance documents* is entirely appropriate, for the same reason that the courts have held that it is appropriate to conduct this same type of review during the development of agency *regulations.* As the United States Court of Appeals for the District of Columbia Circuit explained in 1981 (in an opinion by Judge Wald):

> "The court recognizes the basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy. He and his White House advisers surely must be briefed fully and frequently about rules in the making, and their contributions to policy-making considered. The executive power under our Constitution, after all, is not shared—it rests exclusively with the President.
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> * * *
>
> "The authority of the President to control and supervise executive policy-making is derived from the Constitution; the desirability of such control is demonstrable from the practical realities of administrative rule-making. Regulations such as those involved here demand a careful weighing of cost, environmental, and energy considerations. They also have broad implications for national economic policy. Our form of government simply could not function effectively or rationally if key executive policy-makers were isolated from each other and from the Chief Executive. Single mission agencies do not always have the answers to complex regulatory problems. An overworked administrator exposed on a 24-hour basis to a dedicated but zealous staff needs to know the arguments and ideas of policy-makers in other agencies as well as in the White House."

Sierra Club v. Costle, 657 F.2d 298, 404, 405–06 (D.C. Cir. 1981).[25] In that decision, the D.C. Circuit upheld the appropriateness of discussions between the White House and the Environmental Protection Agency, regarding a draft Clean Air Act rule. These discussions took place—and EPA issued the rule—in 1979, during the Administration of President Carter.

The Executive Order's Non-Guidance Provisions

In addition to providing an opportunity for interagency review of draft guidance documents, the recent Executive Order makes several (non-guidance related) process improvements. As is the case with the guidance amendments in the Executive Order and the new Bulletin, these process improvements are designed to encourage good-government practices. Because there has been some confusion in the press and elsewhere as to the meaning and impact of these changes, let me briefly go through them.

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[23] OMB made this same general point in March 2002 when OMB asked the public to identify examples of "problematic guidance documents" that would be potential candidates for reform. Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, 67 FR 15014, 15035 (March 28, 2002) ("problematic guidance might be improved by interagency review").

[24] Office of Management and Budget, Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, *id.,* 67 FR at 15035.

[25] *See also Chevron v. NRDC,* 467 U.S. 837, 865 (1984) ("an agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely on the incumbent administration's views of wise policy to inform its judgments").

i. Regulatory Policy Officers

Concerns have been raised about the provisions in Executive Order 13422 regarding Regulatory Policy Officers. The initial point that should be made is that such officers are *not* new; when he issued Executive Order 12866 in 1993, President Clinton directed each agency head to designate a Regulatory Policy Officer within the agency. Nor is it new that, under the recent amendment, Regulatory Policy Officers will be Presidential appointees. While the original E.O. 12866 did not require that agency heads choose a Presidential appointee to be the agency's Regulatory Policy Officer, the fact is that, in many departments and major agencies, the agency head did choose a Presidential appointee to serve as the Regulatory Policy Officer.

And, the term "Presidential appointee" should not be confused with "political appointee." Presidential appointees are appointed by the President, whereas agency heads appoint "political appointees" who are in the non-career Senior Executive Service or are under Schedule C; these agency-head appointees are *not* Presidential appointees. Moreover, neither the President nor an agency head can create a Presidentially-appointed position in an agency. Rather, only Congress can do so. And, when Congress does create a Presidentially-appointed position in an agency, Congress usually provides that this appointee shall be subject to Senate confirmation (a PAS official). Thus, by requiring that agency heads designate a Regulatory Policy Officer from among the agency's Presidential appointees, the President is ensuring that, in most (if not all) cases, the Regulatory Policy Officer will be a PAS official.

In addition, concerns have been raised that Executive Order 13422 may require each agency to establish a new "Regulatory Policy Office" that would be headed by the agency's Regulatory Policy Officer. I would like to allay such concerns by explaining that this reference to an "Office" was a typographical error. The reference should have been to a Regulatory Policy "Officer" rather than "Office"; the Executive Order is being implemented accordingly.

I would also like to make three other points regarding the Regulatory Policy Officers. First, Executive Order 13422 places no restrictions on an agency head's discretion in choosing which Presidential appointee within the agency to designate as the agency's Regulatory Policy Officer. It is the agency head's decision to make.

Second, some have raised a concern that the deletion by Executive 13422 of the "report to the agency head" phrase (that had been in Executive Order 12866) means that the Regulatory Policy Officer will no longer report to the agency head. This is *not* correct. The deletion of this language does not change the fact that the Regulatory Policy Officer reports to the agency head. As before, the agency head continues to be the official who designates which official shall serve as the agency's Regulatory Policy Officer, and that designated official will continue to report to the agency head in performing this role, just as that official reports to the agency head in performing his or her other responsibilities. The "report to the agency head" phrase was deleted (as indicated above, without substantive impact) in the course of amending the Executive Order's provision on the Regulatory Policy Officer to include the requirements that the Regulatory Policy Officer be a Presidential appointee, that the agencies need to inform OMB of the designations, and that the agencies need to provide OMB with annual updates on the designations.

Third, some have suggested that the designation of an agency official as the Regulatory Policy Officer means that these officials (in the case of PAS officials) must be subject to a new Senate confirmation. My understanding is that an official's designation as the Regulatory Policy Officer does *not* require that the official be subject to a new Senate confirmation. PAS officials periodically are assigned additional responsibilities (either through statute, executive order, or otherwise), and the assignment of such responsibilities do not require these officials to be confirmed again.

ii. Commencement of a Rule-making

Executive Order 13422 amends Executive Order 12866 to require that an agency's commencement of a rule-making be either authorized by the agency head or approved by the agency's Regulatory Policy Officer. As explained above, most if not all of the Regulatory Policy Officers will be—as they generally have been over the years—Presidential appointees who are subject to Senate confirmation. In practice, then, this will mean that, in most if not all cases, an agency's commencement of a rule-making will be authorized or approved by an agency official who is appointed by the President and subject to Senate confirmation.

iii. Aggregation of annual costs and benefits in the Regulatory Plan

Section 4 of President Clinton's Executive Order 12866 established a "Planning Mechanism" that includes an annual *Regulatory Plan* that reports the most significant regulatory actions anticipated in the coming year and thereafter, along with the agency's estimate of *each rule's* anticipated benefits and costs. Executive Order

13422 amends this section to ask agencies, in addition, to *aggregate* the estimated costs and benefits of the individual regulations. While the interested public could always sum-up for themselves the cost and benefit estimates for each of the individual rules, this amendment enhances the transparency of the annual *Regulatory Plan* by requiring the agencies to do the aggregation.

iv. The Encouragement of Agencies to Consider Formal Rule-making

Another of the amendments in Executive Order 13422 encourages rule-making agencies to consider using the Administrative Procedure Act's formal—rather than informal—rule-making procedures for the agency's resolution of complex determinations. Agencies already had the option of using the APAs' formal rule-making procedures, and this amendment simply encourages them to consider the use of a tool that has been—and remains—available to them.

v. Market Failure

Executive Order 13422 amended Section 1(b)(1) of Executive Order 12866, which was—and remains—the first of that Order's "Principles of Regulation." As recently amended, Section 1(b)(1) now states that: "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem." Before explaining what this amendment *does* do, I would like to explain first what it does *not* do.

First, the concept of market failure is *not* new to this amendment, but instead has been an integral part of Executive Order 12866 since President Clinton issued it in 1993. Indeed, the overarching "Statement of Regulatory Philosophy," in Section 1(a) of the original Executive Order 12866 (*unchanged* by E.O. 13422), states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as *material failures of private markets* to protect or improve the health and safety of the public, the environment, or the well-being of the American people" (italics added). Furthermore, the first "Principle of Regulation" that was articulated in Section 1(b) of the original Executive Order 12866 reiterated the requirement that each agency "identify the problem that it intends to address (*including, where applicable, the failures of private markets or public institutions that warrant new agency action*) as well as assess the significance of that problem" (italics added).

Second, the recent Executive Order does *not* make the identification of a market failure the only basis on which a federal agency can justify regulatory action. The revised section also encourages agencies to identify any "other significant problem it intends to address." For example, important social benefits are provided by the federal regulations that govern the delivery of federal assistance to disaster victims, but these regulations do not address a market failure, per se. Moreover, the recent Executive Order leaves untouched the provision in Executive Order 12866 that expressly directs federal agencies to "promulgate. . .such regulations as are required by law, [or] are necessary to interpret the law." In many cases, when a federal agency is issuing a regulation, the agency is doing so for just those law-based reasons, and this will continue to be the case; nothing in Executive Order 13422 changes this.

Having explained what the revised "market failure" language does *not* do, I would like to now explain what it actually *does* do, which is two relatively modest things.

First, Executive Order 13422 states that the agency "shall identify *in writing*" the problem—whether it is a market failure "or other specific problem"—that the agency "intends to address" through regulatory action. Stating explicitly that federal agencies shall identify "in writing" the problem that the agency is seeking to remedy through regulatory action does *not* impose a new requirement on rule-making agencies. An agency should already have been identifying in writing the precise nature of the problem that the agency is seeking to remedy through regulatory action, *in order to assist the agency in its own analysis of whether regulatory action is warranted and, if so, which of the available regulatory alternatives would best accomplish the agency's intended result.*

Thus, in order to comply with the original version of Section 1(b)(1) of Executive Order 12866, agencies as a practical matter would have had to make (or at least should have made) this identification in writing. However, even if an agency did not do so, the agency should still have identified the problem that it was seeking to remedy through regulatory action in the preamble to the proposed rule (to assist the public in understanding the agency's proposal and in offering their comments on it) as well in the preamble to the final rule (to persuade the public, Congress, and the courts that the agency has exercised its regulatory authority in a reasonable and

well-considered manner). In sum, the requirement that agencies identify the need for the regulation in writing is a good-government measure. It encourages greater transparency in rule-making, by helping the public and others understand the problem that the regulation is intended to address, enabling more informed comment on whether the proposed rule will likely meet its objectives and whether there are other, better alternatives to address the identified problem.

Second, in order to increase the transparency of Executive Order 12866, Executive Order 13422 incorporates into Executive Order 12866 a reference to three classic examples of what constitutes a "market failure"—namely, externalities (which justify, e.g., the regulation of pollution), market power (which justify, e.g., the regulation of the rates charged by natural monopolies, such as local gas and electricity distribution services), and lack of information (which justify, e.g., the nutritional labeling requirements for packaged foods). These three examples of market failure are *not* new to the Executive Branch's implementation of Executive Order 12866. To the contrary, three years after President Clinton issued Executive Order 12866 in 1993, these examples were included in the discussion of "market failure" that was contained in the 1996 "Economic Analysis of Federal Regulations under Executive Order No. 12866" document that former OIRA Administrator Sally Katzen (working with former CEA Chairman Joseph Stiglitz) issued to federal agencies for their use in meeting the analytical requirements of Executive Order 12866 (as well as those of the *Unfunded Mandates Reform Act* and the *Regulatory Flexibility Act*).[26]

In its Part I on "Statement of Need for the Proposed Action," the 1996 "Economic Analysis" document had a Section A on "Market Failure," which provided separate descriptions of "Externality," "Natural Monopoly," "Market Power," and "Inadequate or Asymmetric Information." The 1996 "Economic Analysis" document also included the following introductory discussion:

> "I. STATEMENT OF NEED FOR THE PROPOSED ACTION
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> "In order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure. If the problem does not constitute a market failure, the analysis should provide an alternative demonstration of compelling public need, such as improving governmental processes or addressing distributional concerns. If the proposed action is a result of a statutory or judicial directive, that should be so stated.
>
> "A. Market Failure
>
> "The analysis should determine whether there exists a market failure that is likely to be significant. In particular, the analysis should distinguish actual market failures from potential market failures that can be resolved at relatively low cost by market participants. Examples of the latter include spillover effects that affected parties can effectively internalize by negotiation, and problems resulting from information asymmetries that can be effectively resolved by the affected parties through vertical integration. Once a significant market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure."

Moreover, the three examples of market failure that are now referenced in the amended Executive Order 12866 (i.e., externality, market power, and lack of information) were contained in the draft Circular on regulatory cost-benefit analysis that OMB issued for public comment and peer review in 2003, and they are contained in the final Circular A–4 that OMB issued later that same year (and which remains in effect).[27]

And, thus, the use of these three market failure examples in the implementation of Executive Order 12866 is *not* new. Moreover, Executive Order 13422 did *not* substantively change the first "Principle of Regulation" in Executive Order 12866 or how this Principle is implemented by the Executive Branch. Instead, all that happened as a result of Executive Order 13422, with respect to these three examples

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[26] Memorandum for Members of the Regulatory Working Group from OIRA Administrator Katzen, "Economic Analysis of Federal Regulations under Executive Order 12866 (January 11, 1996), available on OMB's website at *http://www.whitehouse.gov/omb/memoranda/rwgmemo.html.* As Administrator Katzen stated in her transmittal memorandum, the "Economic Analysis" document "represents the results of an exhaustive two-year effort" by an interagency working group chaired by Joseph Stiglitz of the Council of Economic Advisers and Steve Kaplan, the-then General Counsel of the Department of Transportation.

[27] Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations, 68 FR 5492, 5514–15 (February 3, 2003); *Informing Regulatory Decisions: 2003 Report to Congress on the Costs and Benefits of Federal Regulation* (2003), at pages 121–122 (available on OMB's website).

of market failure, is that they are now mentioned in Executive Order 12866 itself (rather than only in the implementation documents). In other words, the recent amendment has simply increased the transparency of Executive Order 12866.

Some have expressed concern that this amendment to Executive Order 12866 could prevent agencies from issuing regulations to protect public health and safety, but this is not correct. Many of the most significant regulations that agencies issue are, in fact, driven by—and are in response to—market failures. As the 1996 OMB "Economic Analysis" document noted, "[e]nvironmental problems are a classic case of externality," and this Administration has issued a number of significant environmental regulations aimed at addressing environmental externalities, including EPA's Clean Air Interstate Rule (CAIR) and its Non-road Diesel Engines Rule. Similarly, regulations to protect homeland security, such as FDA's recent regulations under the *Public Health Security and Bioterrorism Preparedness and Response Act,* respond to inadequate private market incentives to respond to potential terror threats.

Another type of market failure that is mentioned in the amendment made by Executive Order 13422 stems from lack of information. An example of a regulation that is justified by the "lack of information" market failure was the Food and Drug Administration's recent regulation that requires the nutritional labels on packaged foods to display the amount of trans-fats in them. This labeling requirement is estimated to have considerable public health benefits, by providing consumers important information with which they can make purchasing decisions. Moreover, this rule was the subject of a "prompt letter" that former OIRA Administrator John Graham sent to HHS in 2001 encouraging the agency to issue a rule to require the labeling of trans-fats.[28]

Finally, in both the CAIR and trans-fats rules, identification of a market failure, rather than a specific directive from statute, was the driving force behind the issuance of regulations that are expected to have significant public health and quality of life benefits.

Moreover, as noted above, nothing in this amendment to E.O. 12866 precludes agencies from justifying regulations on grounds other than the failure of private markets. Nor does it preclude agencies from justifying regulations on the ground that Congress has required the agency to promulgate regulations to address a particular situation, or on the ground that the regulations are necessary to interpret the law, or on the ground that regulations are necessary to address a compelling public need.

Thank you again for this opportunity to testify. I hope that I have been able to clarify the purpose of the new Good Guidance Bulletin, and the recent amendments to Executive Order 12866. As I noted at the beginning of my testimony, the Executive Order and Bulletin share a common goal: namely, the good-government objective of improving the way that the Federal Government does business—by increasing the quality, public participation, and accountability of agency guidance documents and their development and use.

I would welcome any questions that the Subcommittee has.

BIOGRAPHY FOR STEVEN D. AITKEN

Steven D. Aitken was designated by the President to begin service on June 3, 2006, as the Acting Administrator of the Office of Information and Regulatory Affairs (OIRA), an office within the Office of Management and Budget. He served as OIRA's Acting Administrator for the following ten months (his service ceased in early April, 2007, when Susan E. Dudley was sworn in as OIRA's Administrator).

Prior to serving as OIRA's Acting Administrator, Steve was Deputy General Counsel at OMB and, prior to becoming Deputy, he was an Assistant General Counsel at OMB. In total, he has served at OMB for nearly 18 years. He has also served in the U.S. Department of Justice as a trial attorney in the Civil and Antitrust Divisions, and he served two judicial clerkships, one in 1986-1987 for Judge (now Chief Judge) Douglas H. Ginsburg of the U.S. Court of Appeals for the District of Columbia Circuit and the other in 1984–1985 for Justice (later Chief Justice) Christopher Armstrong of the Massachusetts Appeals Court. He has a Bachelor's degree in Government from Harvard College and a law degree from Harvard Law School.

Steve lives in Washington, D.C., with his wife and son.

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[28] Letter from OIRA Administrator Graham to the Department of Health and Human Services regarding trans fatty acids (September 18, 2001) (available on OMB's website).

DISCUSSION

Chairman MILLER. Thank you, Mr. Aitken. I want to announce a policy this morning. In the first couple of meetings of this subcommittee, I have had a hard time overcoming my Southern mother's teaching that interrupting people was bad manners. I think all of us struggle as adults to figure out what part of what our mother taught us we need it ignore as adults. But we do need to keep fairly close to the time allotments. You were fine. You were just a few seconds over. Mr. Rohrabacher was actually just a few seconds over in his opening remarks as well. In his opening round, I will ask for questions for seven minutes, my questions and your answers, Mr. Rohrabacher for seven minutes. If any other Members appear, they will have turns to ask questions for five minutes. But we do need to keep fairly closely within that time limitation, and I will bring the gavel down as necessary, hoping that in fact C–SPAN is not broadcasting this and my mother is not watching it at home.

EXECUTIVE ORDER CONSULTATION PROCESS

Mr. Aitken, in your written testimony you said the OMB believes that federal agency guidance should be developed, issued and used through an agency's adherence to procedures that ensure quality, transparency, public participation, coordination and accountability. All those sound laudable, I agree with all of them, but I am wondering how those standards were applied and actually developed in this executive order that we are discussing now. Were there meetings with which agencies about them? When did those occur? Were there any public comments sought? Was there correspondence with outside parties? Could you tell me briefly what kind of consultation occurred in developing this order?

Mr. AITKEN. Thank you for the question. The order was developed in accordance with the standard process that the executive branch has for the development of executive orders and that process is set out in an executive order itself. I believe the number is Executive Order 11030 that has been in place for several decades. And it provides for a process whereby OMB consults with other agencies about a proposed executive order and the executive order could be proposed by an agency, another office, by OMB, and those consultations then feed into an internal deliberative process that results at the end of the day in a proposal being made to the President and it is then the President's decision on whether to move forward with the proposed order or not. That standard practice, which was followed here, does not involve putting out a draft of an executive order for public comment. That is simply not the practice that has been applied for decades in the development of executive orders. In this case, the agencies were consulted per the standard process and their views were requested and taken into account.

Chairman MILLER. You said that there was not a draft put out for public comment. I assume that you didn't get it just perfect the very first time, that there were various iterations of the executive order? Am I correct in assuming that?

Mr. AITKEN. Yes. I can't really get too much into the details of the executive order process in regard to the substance or the discussions that occurred internally, but yes, as is the case with exec-

utive orders, and OMB does handle that process, I am familiar with it, executive orders typically go through a number of drafts in response to comments and further thought.

Chairman MILLER. When you say you can't comment, is it because you are not familiar, you don't know?

Mr. AITKEN. It is because it is just an internal deliberative process and the standard practice is not for the executive branch to reveal the internal deliberations that resulted in an executive order.

Chairman MILLER. Mr. Aitken, we have a point of disagreement about what Congress's authority is and what the internal deliberative process protects from disclosure to Congress, and I am afraid if you take that view, we may end up having several hearings about this issue. Did you—I am sorry. So it is your intention not to discuss further what the procedures were in developing this draft, the various drafts, who was consulted, what documents were generated, were there internal memoranda, correspondence, e-mails, were there such documents?

Mr. AITKEN. Oh, yes. The standard executive order process in the OMB's general counsel's office is a lead within OMB for the interagency clearance of executive orders, so I am very familiar with that process. It typically involves the submission by an agency or an executive branch office to OMB of a proposed executive order, the circulation of that proposal to agencies and offices who would be interested in that order for their review and comment——

Chairman MILLER. But you do not intend to testify today to who made which suggestions, observations, criticisms, concerns? You view that as not within the information that Congress may seek of the executive branch?

Mr. AITKEN. We are——

Chairman MILLER. That is a bad course we are on if that is the view you take.

Mr. AITKEN. I think what I am offering, again in my capacity as the former acting administrator and as a long-time OMB career employee, is that those deliberations which ultimately lead to the proposals to the President for action are internal deliberative communications. They are privileged. We would not release those for example in response to a FOIA request or litigation, and my experience has been that we have not released those deliberations to the public or that we have been requested or provided those in the past, that is. It is just not my experience.

Chairman MILLER. That has been my experience too, but a request from a committee of Congress is not the same as a FOIA request. There are cases, as I am sure—I hope you are aware—maybe you aren't aware. The courts have dealt with this issue. There is an internal deliberative process. The court says it has very slight weight. If there any need for the information, the concern about finding the truth overcomes any concern about protecting confidentiality, and if there is any suggestion that there was an improper—that the executive agency action was based upon any improper consideration, there is no privilege or immunity at all. This is not a FOIA request. Now, I am afraid that we are going to have to have another hearing to discuss these processes, and I certainly think that we are going to now request the agency a great many documents. So I would urge you to, when you get back to your of-

fice this afternoon, look at the law on internal deliberations and consider carefully that this is a committee of Congress asking, not a FOIA request.

Mr. AITKEN. I understand that, and I will do so. I mentioned the FOIA in part just because of the Congressional recognition in the enactment of the FOIA of the importance of confidential deliberations for improving government decision-making. Also, it is my experience that the executive branch over the years through decades has not received requests from Congress for the internal deliberations leading to executive orders, so for me, this is an unprecedented experience and it is just——

Chairman MILLER. Well——

Mr. AITKEN.—being here today, I am not in a position to be able to——

Chairman MILLER. Why you did what you did strikes me as something Congress has every reason in the world to ask.

Mr. AITKEN. Yes, I am happy to answer any questions about the order itself, and I think both with respect to the order and other issues, I think it is best or at least I am here to be able to explain what these provisions mean, why they are there, and I think at least the confidential deliberate process tries to protect the ability of people to have a dialog, and my sense is that——

Chairman MILLER. And I know you have a distinguished legal education and I know that you have studied the law of privileges and you know that there is a tension between encouraging confidentiality, encouraging candor, and the need to find the truth. There are some privileges that are absolutely respected. Well, actually there are very few that are absolute. The attorney-client privilege, for one, is a very strong privilege but the courts have struck a different balance with respect to internal deliberations that the courts perhaps respect the confidentiality, the candor of those discussions over a concern based on—or an inquiry based on idle curiosity, but if there is a need to know, whatever privilege there may be gives way. Again, I urge you to look at your law books this afternoon, and I assure you, I feel confident we will be asking for further documents based upon our conversation just now.

Well, I have many questions that you may or may not answer. Was anyone outside of—I am sorry. I have violated my own rule slightly.

Mr. ROHRABACHER. I think we need to interrogate you into what mental processes you were going through when you violated that rule you had set down. We need to question whether or not that was a planned move or whether this is just something that you just happened to do because you were being the Chairman and you were asking some questions, but we need to get you under oath to testify to see if you actually were motivated to break that rule that you just had.

With that in mind, Mr. Aitken, you have worked for the Office of Management and Budget for how many years?

Mr. AITKEN. In May it will be 18 years.

Mr. ROHRABACHER. Eighteen years, so you were actually there and overseeing legal type of analysis of things that were going on even during the Clinton Administration. Is that right?

Mr. AITKEN. That is correct.

Mr. ROHRABACHER. Did anyone ever put you under oath and start inquiring about the internal deliberations during the Clinton Administration when they were trying to issue executive orders or was that normally accepted that basically the President has a right to issue an executive order and then has a right to have internal deliberations to what that executive order should say?

Mr. AITKEN. My experience was that OMB had not received requests, at least to my recollection had not received requests during the Clinton Administration or even during prior years in this Administration for the internal deliberations regarding an executive order.

Mr. ROHRABACHER. For example, in the Clinton Administration, you had the wording of the executive order, each agency shall identify the problem that it intends to address including where applicable "the failures of the private markets" or public institutions that weren't new agency action as well as access to the significance of that problem. Now, that wording was changed, which seems to be a big problem now. Instead of the failure of private markets, it seems to be that the big problem is that they changed that to say each identify shall identify in writing, so they are identifying this in writing now, the specific market failures as compared to failures of the private market, and then we are requiring them to do it in writing rather than just in an oral report. Now, I guess we really need to know whether changing that wording whether or not there were memos going back and forth and we got to make sure that you spent a lot of time now searching those records to see about who wrote that and whether or not that person, you know, may or may not have had the best interests of the country at heart when he wrote that as compared to when the Clinton Administration wrote those words, "failures of private markets," that nobody questioned that. I guess that is what we are talking about today, and your recollection is that nobody bothered to ask anybody about the wording of "failures of the private market" as compared to "market failures" when you worked at the OMB under President Clinton. Is that right?

Mr. AITKEN. That is correct.

Mr. ROHRABACHER. No one requested any information then. Would you be surprised if there were directives issued by a political party that every committee and subcommittee should find something that they can issue ominous-sounding statements about and requesting voluminous information of the Administration trying to catch the Administration in a mistake and then making it into more than a mistake, more than just going over a minute, but a calculated attempt to break the rules? Would you be surprised if a group of people who are running for political office might try to use the Congress as a forum to create a false impression for the voters in the next election? You don't have to answer that. Thank you very much.

You know, I will just have to say that this, what we are talking about today and what we are going through today is totally consistent with what, as I say, happens, is happening in other committees, and President Clinton fires every U.S. attorney, every one immediately without question, and nobody raises an eyebrow because they know that he has a right to fire those U.S. attorneys, and the

President has a right to issue executive orders. President Clinton issues an executive order, talks about the failures of private markets and of course nobody raises the issue but this President changes the wording to say "market failures" and requires it in writing and all of a sudden now we have got all these requests for documents.

You know, when the attorney general started answering questions about what was the President's prerogative, they found that he didn't say exactly the things that were right in describing why the President made a decision even though everyone acknowledges the President has every right to make that decision and now they have made that into a big brouhaha. I am not necessarily someone who likes this attorney general or even likes this President, to tell you the truth, but I can certainly believe that we need to be tackling real problems rather than political posturing. I would suggest that there is a pattern here. The pattern isn't that we have changed the wording of "failures to private markets" in an executive order to "market failure" and require it in writing. That is not the pattern. The pattern is that we are challenging the President's authority hoping to find a mistake when he answers that question and then making a lot of political hay about it.

I appreciate you being here. You are not a Republican or Democrat appointee. You are actually a professional, having served in a high place in both the Clinton Administration and the Republican Administrations, but let me thank you for your professionalism.

And let me note that I am intentionally not going over my time, and this has been calculated now to make sure that the failure of the Chairman to go over his time is just—is highlighted, so I will quit right there, Mr. Chairman.

Chairman MILLER. Actually, Mr. Rohrabacher, I went over two and a half minutes. If you would like to go on another two and a half minutes, you go right ahead.

Mr. Aitken, I assume that my staff will punch me in the ribs when it comes close to five minutes. I know that you had expressed some concern or reservation about telling this committee some of what the OMB considered in issuing this executive order and I had somehow confused transparency with candor, but can you tell me at least when the first draft of this proposed regulation was circulated and to whom? Who saw it?

Mr. AITKEN. The order had been in development for some time. I don't have a specific recollection of when it was first circulated or to which agency. That would be typically done by a career employee within the OMB counsel's office in consultation with others and so, you know, apart from it being done in the standard process, I don't have a recollection exactly, you know, what time or exactly to whom but it was the standard process that was used.

Chairman MILLER. Do you know approximately what month and year?

Mr. AITKEN. Since I haven't looked into that, I hesitate to say just because I haven't looked into that history recently.

Chairman MILLER. Was it circulated to anyone outside of the Administration?

Mr. AITKEN. So far as I know, no, it was not.

Chairman MILLER. No one outside of the Administration was shown, or there was no discussion with anyone outside the Administration about the proposed executive order?

Mr. AITKEN. I am not aware of any such discussions. I can't say that they didn't occur but I am not aware of them.

Chairman MILLER. Who within the Office of Management and Budget, or OMB, or any other agency of the government was involved in developing the draft or changing the draft as drafts went forward?

Mr. AITKEN. In OMB, it would be—a variety of offices are involved in executive orders, depending on the subject matter, because OMB in the standard process sends a recommendation memo to the President. It receives a fair level of clearance through a number of offices. And so, again, the standard process was used but I don't have a recollection of exactly, you know, who all was consulted although as typically the case, it was a broad range of people within OMB.

Chairman MILLER. Mr. Aitken, my understanding is that we didn't specify you as a witness that we wished—nothing personal, but we asked OMB and OIRA to produce a witness who could talk to us about the process, how this was done. It is somewhat surprising, knowing that that is why we asked for a witness to be sent forth, that you are so unfamiliar with the process and that is exactly what we told you we wanted to hear about.

Mr. AITKEN. My understanding was that when this hearing was first raised as a possibility in early March when I was the acting administrator, there was naturally an interest in my testifying, but when the hearing was then moved to late April and then when Ms. Dudley was sworn in as the OIRA administrator, my understanding is that OMB did reach out to the Subcommittee staff to ask whether the Subcommittee staff, or the Subcommittee rather, wanted me to testify as I was no longer the acting administrator. My understanding is that the response that we received back is that the Subcommittee did want me to testify even though I was no longer the acting administrator.

Chairman MILLER. And we understood the reason you were being offered was that you were there at the time, that Ms. Dudley couldn't talk about it because she wasn't there at the time, but I am not sure there is much further to be gained by this.

Your statement in your testimony, OMB believes that federal agency guidance should be developed, issued and used for an agency's adherence to procedures that ensure quality, transparency, public participation, coordination and accountability. Do you believe that those considerations, those goals should not also apply to developing an executive order?

Mr. AITKEN. Well——

Chairman MILLER. You can—I will tell you what. Why don't you answer that in my next round of questioning?

Mr. Rohrabacher.

Mr. ROHRABACHER. Thank you very much. So you were there during the Clinton Administration, did President Clinton discuss when he changed this wording in his executive order from failures of private markets to whatever it was before that to now it has

been changed to market failures? Did he ever discuss that with any other interest groups in this town?

Mr. AITKEN. My understanding from the testimony that Ms. Katzen provided in February, I believe, is that—and she was the OIRA administrator at that time, is that she, according to her testimony, did have discussions.

Mr. ROHRABACHER. Oh, she did?

Mr. AITKEN. According to——

Mr. ROHRABACHER. So you mean the President before he issues an executive order actually talks to people outside the government? What kind of influence could they possibly have? My gosh, people outside the government are trying to maybe have an input into what government policy should be in terms of executive orders. Don't you see this as a threat to democracy in this country? No, you don't have to answer that. Were there documents ever requested about these discussions that President Clinton had with the outsiders when he changed—when he came up with the phrase "failures of private markets" versus "market failure"?

Mr. AITKEN. I am not aware that there were any such requests.

Mr. ROHRABACHER. Now, but you don't know—you said "I am not aware," so we might have to request those documents as well, Mr. Chairman, of what happened during the Clinton Administration to see if my gosh, there were some incredible insidious interest groups at work there too. Let us see. Now, let me ask you this. You worked for Clinton and Republican Administrations. It is your understanding that when you talk about executive orders, which is what the President is given the right to do under the Constitution, that the process that he develops that he thinks is the best way to develop an executive order, that that is pretty well left up to the President to decide what process he is going to have and what people will be in that process as compared to having, let us say, the legislative branch in our Constitution suggesting they have the right to establish that process?

Mr. AITKEN. It has been the process that has been established by the Presidents and——

Mr. ROHRABACHER. Based on constitutional authority granted to him. Is that right?

Mr. AITKEN. That is correct.

Mr. ROHRABACHER. Does the Constitution permit the legislative branch to determine that for the President about the processes and have to have approval on that?

Mr. AITKEN. I wouldn't want to express an answer here just because——

Mr. ROHRABACHER. Okay. It is just that what we are talking about here is not the policy. I think the founders of the Constitution wanted us to be talking about policy, not trying to catch somebody as if they made a mistake in the process of how they determined that policy, because one is where you destroy people and would stifle debate on policy and the other approach is that you are discussing the issue at hand and trying to dissection what is best for the country, what policy is best for the country. I think our founding fathers were very astute when they understood that politics might get in the way if we ended up discussing policy—or our process rather than policy, and unfortunately again I see this dis-

turbing ominous trend in this town where people don't want to discuss the policy but they want to catch somebody in a mistake while trying to recall the exact process of how a policy was decided upon instead of just discussing whether that policy is a good policy or not, and if this was just happening in this subcommittee I think that we could just sort of shrug our shoulders and say that this is not—you know, this is something that is very legitimate here, somebody really just wants to go down that road. But it seems to be happing throughout the legislative branch now as compared to what happened of course during the Clinton years when no one suggested the President didn't have these rights to make up his own mind in a process that he had established.

So with that said, I appreciate your testimony, and I appreciate your service to the country. You are obviously someone who takes your job very seriously and you are the type of person that is not a partisan. You have worked hard for both Democratic and Republican administrations and I am sorry that quite often people like yourself get caught in the middle of different political power plays. I appreciate it.

Chairman MILLER. Mr. Rohrabacher, you can take that two and a half minutes any time that you would like.

We seem to have stumbled on the only area that was not the subject of Congressional inquiry in the last six years of the Clinton Administration. There were two subpoenas issued by the Government Reform Committee a day for every day Congress was in session in the last six years. There were 4,000 pages of documents produced a day in the last six years for every day that Congress was in session. And Mr. Aitken, let me make it clear to you, and I don't think that you have any doubt about this, consultation is a good thing. We urge that. I hope you did talk to people. I hoped you talked to people within the Government. I hope you talked to people who deal with the Government. What we want to know is what was said, that it be open, that yes, there be a debate and a discussion but that it not be in secret. That is why I am asking the questions. I want to know what the concerns were that this executive order was designed to address.

Mr. AITKEN. And I can address that.

Chairman MILLER. Well——

Mr. AITKEN. As I indicated in my prepared testimony——

Chairman MILLER. Well, that is why I asked the question, who was involved with the discussion and what they had to say, and just describing generally what were the concerns were and the objectives were does not get us at what the concerns were in this order and that is why I am asking the questions.

MARKET FAILURE PROVISIONS

Okay. There are other parts of the order—you testified that market failure is not a new consideration, and as I understand market failure, it is the argument that the market hasn't failed; if we just leave it alone it is going to the fix the problem without Congress doing anything, or a regulatory agency doing anything. Is that basically the idea behind market failure?

Mr. AITKEN. As the 1996 Best Practices Guidelines that Administrator Katzen issued explained the rationale of market failure,

which is one but not the only rationale for regulatory action, is that sometimes the government needs to step in because private markets are not addressing the situation. For example, in the FDA nutritional labeling rule——

Chairman MILLER. So the way I described the concept of market failure is essentially right? The market hasn't failed. If we leave that market alone, it is going to fix the problem without any intervention by government. That is the idea behind market failure being a criteria, and has the market failed, is the market not going to fix this on its own. That is what market failure is, right?

Mr. AITKEN. That is correct. If the market is going to address a certain situation, then it is not——

Chairman MILLER. Leave it alone?

Mr. AITKEN. Yes.

Chairman MILLER. I was part of the debate last week, and I think we will have this debate replayed again and again on whether shareholders should have an advisory vote on executive compensation at public corporations in America, and the argument it, the argument against the legislation was, the market will fix this. Now, that seems to me to be a market-failure argument, and every time that Congress enacts legislation to protect public health, to require FDA to inspect and assure sanitary conditions and there are public health consequences of what is being put in the marketplace, Congress has decided that the market is not working sufficiently well and we need to do something about it. So it seems that whenever we have given an agency rule-making authority, not just rulemaking authority, we have directed them to make rules, to carry out a statutory mandate, Congress has already decided the market is not doing this well enough and usually over the express argument that the market is doing it well enough. Now, can you tell me, is there a clear, rigorous test that we can look at, that we can understand for when the administration, the executive branch, the various agencies, the OIRA or the RPOs will apply to determine if the market has failed and the government needs to intervene through regulation?

Mr. AITKEN. In terms of statutes, if Congress has directed an agency to issue a regulation, then the agency must issue the regulation. There is nothing in the executive order either as issued by President Clinton or the recent executive order that overrides any statutory directions to agencies. If Congress has made a decision that a regulation is necessary, the agency must issue the regulation. The issue of market failure comes up in a situation in which an agency has discretion; Congress has not made a decision that the agency has to issue a regulation. Instead, the agency has permissive regulatory authority and the question is whether the agency decides in its discretion to exercise that authority, and as reflected in the 1996 guidelines that Administrator Katzen issued and in OMB Circular A-4, which we went through public—and there was some comment on, the criteria for market failure as a rationale addresses whether there is a problem out there that, one, if a problem exists, two, is it because the markets have not worked to address it, and three, is it something that the markets could not address. If that is the case, then that rationale for regulatory action would argue for the agency to act. However, there are other

rationales apart from market failure which the executive order and the recent amendment recognizes——

Chairman MILLER. Mr. Aitken, can you complete this answer at the beginning of my next round of questions?

Mr. Rohrabacher.

Mr. ROHRABACHER. Well, I am not a stickler. I will let you sort of have an extra couple of seconds there. That doesn't—I am not going to throw the book at you if you break the rules.

Chairman MILLER. Mr. Aitken, if you would like to complete it on Mr. Rohrabacher's time, that would be fine.

Mr. ROHRABACHER. That is the type of courtesy that makes this government work, unfortunately. I hope everybody understands that, the point I just made, that is.

Mr. AITKEN. I was just concluding by saying that the guidance that has been out there since as far back as least 1996, the guidance that Ms. Katzen issued, describes the situations in which market failure can provide a justification for regulatory action. Again, as the original Executive Order 12866 provided and as the amended one provides, market failure is not the only justification on which regulatory action can be received. It can occur because Congress has directed an agency to promulgate a regulation and it can occur to address other problems that the agency has identified. That is it.

Mr. ROHRABACHER. Thank you for that answer, and let me note that President Clinton issued the executive order in question here September 30, 1993, which seems to be, if memory serves me, actually very early into his first term of office, and this President has permitted that executive order to stand until very late in his Administration. It seems to me that is perhaps similar to the fact that when—and when Bill Clinton did change this early on into his Administration, as I say, there doesn't seem to have been any of the inquiries made at all into this, into the process of how he came to the decision to issue his executive order. No documents were mandated, no questioning of his motives, only maybe perhaps a discussion of the executive order itself. I don't remember that discussion but it certainly wasn't accusatory in the discussion. It was probably a discussion of the issue itself. That might be the same as when President Clinton fired every U.S. attorney then in position of authority when he became President. Again, no one questioned whether the President had a right to fire those U.S. attorneys and to hire his own people. That is—these are people who serve at the pleasure of the President as granted by the Constitution of the United States. No one asked the President, no one came in and put people under oath and tried to find out if they can determine whether there was any loss of memory in the process, trying to get people and charge with them all kinds of malicious intent if they didn't remember exact details in conversations. Thus, and so there seems to be a change of strategies here, that during the Clinton years Republicans were not pushing on issues like that, and now during—when we have a president of the United States who is a Republican and it is getting close to an election year, now we seem to have a focus on other elements. Rather than policy, we focus on process and trying to see if people's memories are exactly right to see if we can catch them in a mistake.

I will tell you, it would be hard for me, I can't speak for the Chairman or other Members of this body but it would be very difficult for me to answer questions about how I came to a determination as to what my position was going to be on specific issues of the day, whether it was legislation or various issues. It would be very difficult for me to try to search back and found out exactly when I decided on something, and I think that that really does break down the goodwill and camaraderie that we have here in the Congress because people have to assume that we are going to debate the issues and not debate whether somebody is being—what someone's motives were and that is one of rules of thumb here in the House. But I guess that doesn't apply when we are trying to talk about the President versus the legislative branch, or the executive branch versus the legislative branch.

With that, thank you again for your service as being a bipartisan person who worked in both administrations, Democrat and Republican, and tried your very best, and certainly we are not trying to catch you on some lack of memory or making a mistake of memory.

Chairman MILLER. Mr. Aitken, I had really hoped to announce the new policy of being stricter with the time limitations without naming names on who had abused my Southern manners, and I will stick to that intent despite obvious goading.

Mr. Aitken, I agree that if I were asked I voted for something three years ago, trying to reconstruct my thinking at the time would not be easy and I couldn't do it on the spot, but on the other hand, if I had been sent forward from a government agency to answer specific questions as to one at that agency who would know it, I would expect to be prepared. I would expect to refresh my recollection. I would expect to look at the documents. I would not just show up.

Mr. AITKEN. Well, that was not the case in terms of my coming here. I did prepare. I prepared as I had prepared for my testimony in February before the House Judiciary Subcommittee, which was on the same day in fact, just after the hearing that this subcommittee held. I was not aware in coming here that I would be asked specific questions about who was consulted or what the timetable was for the development. I came here prepared and submitted lengthy, comprehensive testimony regarding the issues in the bulletin, regarding the reasons the bulletin was issued, regarding the issues in the executive orders, and consistent with my professionalism as a career OMB employee, I prepared to the best of my ability for testifying today.

TRANSPARENCY PROVISIONS

Chairman MILLER. Let us move on to the transparency considerations again, and we all seem to like transparency, at least the word, and then we have different interpretations what it actually means or requires. The Clinton executive order that apparently somehow escaped being the subject of Congressional subpoena, perhaps because it was in the first two years of the Clinton Administration, did put in place transparency protections. Isn't that right, with respect to OIRA's decisions?

Mr. AITKEN. The executive order does include transparency provisions. Many of those transparency provisions had been in effect for a number of years during the prior Administration.

Chairman MILLER. And it includes showing an original draft of a proposed rule that had come from the agency and how it was changed. Isn't that right?

Mr. AITKEN. That is correct, under the disclosure procedures.

Chairman MILLER. And it required showing what outside parties had commented and what they had to say, what the correspondence was between OIRA and the outside parties. Isn't that right?

Mr. AITKEN. Under the executive order, for rules that under review there are requirements which we adhere to in OIRA for the notice of when meetings are requested from outside parties. Anyone can request those meetings. They are posted on the OMB web site. I can say that during my ten months, we received a number of requests for meetings which so far as I know, we always granted if we had time and——

Chairman MILLER. So essentially all the questions that I have asked you about how this executive order was decided upon are questions that would be public record, would be public with respect to a rule that had gone through OIRA under the Clinton Administration? Isn't that right?

Mr. AITKEN. I am not sure I understand the question.

Chairman MILLER. The questions I have asked you about who was consulted, what they had to say, how was the draft changed, those are all questions that would be public with respect to a proposed regulation under the Clinton executive order? Isn't that right?

Mr. AITKEN. The distinction is that OIRA doesn't review executive orders.

Chairman MILLER. I understand that distinction, but the process I described, the questions I have asked, those are public based upon transparency concerns with respect to proposed rules, right?

Mr. AITKEN. Under Executive Order 12866, President Clinton and this President has continued disclosure procedures about OIRA's reviews of regulations. I am not aware of any president, and I believe that the executive order—and the executive order process was established by President Kennedy. I am not aware that any president has established a process where the President is going to have his executive orders subject to public comment or is going to release the drafts or is going to—I mean, you know, whether it is President Kennedy, President Johnson——

Chairman MILLER. I understand the distinction you are making between executive orders and regulations and you are saying this executive order does not apply to regulations. With respect to regulations, with respect to the Bush Administration's new order, power is given to regulatory RPOs at each agency and which regulatory policy officers, which of these transparency requirements under the Clinton executive order would apply to decisions made, deliberations at the agency level by the RPOs? None of them would, would they?

Mr. AITKEN. The executive order as it was originally issued by President Clinton when he required agency heads to appoint regulatory policy officers did not have any disclosure procedures regard-

ing the regulatory policy officers' activities and that continues today. So since President Clinton issued the order in 1993, there have been no disclosure provisions regarding the regulatory policy officer.

Chairman MILLER. I am out of time, but you can assume that I will ask further questions along these lines.

Mr. Rohrabacher.

CONFIDENTIALITY CONCERNS

Mr. ROHRABACHER. Well, let me note for the record that I am not opposed to transparency at all. I mean, to the degree that the executive order that we are talking about has in some way decreased the transparency, then that is an issue that we should talk about. We shouldn't be talking about who discussed the issue of transparency with the President. We should discuss whether transparency in and of itself is an issue that is right or wrong and whether the executive order went in the right or wrong direction. That is a totally legitimate area of discussion, and I would support more transparency requirements. However, I may be right or wrong in that. That is just my inclination. For example, if we have the same transparency requirements, if we set the same standard for Members of Congress, we would have to say that members of the executive branch would have a right to query Members of Congress as to who they spoke to, every single person that they spoke to about any legislation, specific pieces of legislation that would come up. We are sitting—we are making policy too here, and does the executive branch have a right to query us under oath to find out who we talked to or do the American people have a right to know exactly where we stand? I think the American people have a right to know exactly where we stand on an issue, which half the time Members of Congress, as you know, try to obscure exactly what their positions are to try to make sure they are not making any enemies, so I would be very supportive, Mr. Chairman—if there is something in this executive order that hurts transparency, we could work on that and try to pass some legislation that would insist on transparency. But let us discuss that issue. Let us not discuss how some decision is come to.

Let me get back to that. Mr. Aitken, do you think that Congressional demands, and this—because I may be supportive of those Congressional demands for transparency. Do you think Congressional demands for specific communications within the executive branch would curb the discussions and people wouldn't be quite so frank in their discussions on an issue if they knew everything was going to end up being public? Would that be in the end to the detriment of the public more than just—would that have a negative impact as compared to a positive impact of transparency where we know all the discussions that were going on?

Mr. AITKEN. I think I would like to address that in terms of the confidentiality of the deliberations and the importance of preserving that confidentiality is so that people can have frank and candid discussions, and Congress recognized that when in 1966 in enacting the FOIA statute it preserved the deliberative process privilege. The courts have upheld that. It is important for people

to be able to discuss the issues. If people internally cannot discuss the issues in a frank manner, decisions are——

Mr. ROHRABACHER. I agree with that, but I will tell you on another committee—not another committee, actually this committee but on another subcommittee, we were dealing with reports that were issued by a member of the—someone who worked for the government issued a report on a specific decision that needed to be made and does that person, should we then, when the Administration is trying to make up its mind on something, should we then know what was in that report? I happen to believe in transparency because I happen to believe—and I have backed up the Democrat demands to see that report, and I don't think that would in some way hinder the debate within the Administration if they knew that people when they asked their opinion of various professionals like yourself what the opinion was when it was written down. Now, that is different than talking about private deliberations, I think, but maybe not. Maybe you can clear that up for me.

Mr. AITKEN. I am not familiar with the situation you just mentioned in terms of the report but I can say that having worked at OMB for 18 years in the counsel's office where these issues come up quite regularly, that it is important, as it would be with a judge and a law clerk. I clerked twice. I think judges expect the confidentiality of their——

Mr. ROHRABACHER. Especially for professionals. So if we have a professional who is over at a department or agency and we ask for a report, you know, I frankly think that should be public record and I would oppose the Administration keeping that secret. However, it may make that public employee less, let us say, willing to be totally expressing his points of view if he knew it is all going to be public some day. Is that right?

Mr. AITKEN. That is the concern that underlies the deliberative process.

Mr. ROHRABACHER. Thank you very much.

REGULATORY POLICY OFFICERS

Chairman MILLER. Mr. Rohrabacher, you just used 20 seconds of the two and a half minutes that you have got coming.

Mr. Aitken, you said earlier that RPOs were not new creatures of this executive order, that they existed before. What additional authority is given RPOs under this order?

Mr. AITKEN. As I noted in my prepared testimony, the recent order makes two relatively minor amendments to the provisions. One concerns the regulatory plan. Under the original issuance of Executive Order 12866 by President Clinton, it was the agency head who had to personally approve the regulatory plan. Under the revised order, it is either the agency head or the regulatory policy officer that would sign off on the agency's regulatory plan, which is the agency's once-a-year compendium of the agency's most important regulatory initiatives. Also, the executive order, the recent one, provides that either the agency head or the regulatory policy officer has to sign off on a commencement by an agency of a rule-making.

Chairman MILLER. When a professional employees of an agency want to initiate rule-making, the RPO can decide no, we are not

going to do that? That is correct, right? That is the power of the RPO now under this order?

Mr. AITKEN. The order provides that in an agency, it is ultimately the presidential appointees who have to decide what regulatory activities the agency wants to engage in. This is not a new principle for the executive branch. I know that in the transition from the first President Bush to President Clinton, one of the first things that was done by the incoming OMB director, Leon Panetta, was to issue a memo to all agencies saying that there is a new president and agencies are not to issue new regulations unless they are approved by the agency head, who is appointed by the President, or by somebody else who has been appointed by the President. And that is to reflect that, that it matters who is elected President, and in the executive branch, it is not solely the career employees who have the authority to issue regulations or decide how governmental power will be organized.

Chairman MILLER. And I don't think we want to be entirely controlled by bureaucrats. We do not want government by bureaucrat or by platonic guardians. We do want the democratic processes to matter. But what are the transparency requirements, provisions for RPO decisions not to initiate rule-making? Do any of the transparency provisions that apply to OIRA apply to the RPO when the RPO determines not to initiate rule-making? Will anyone find out that the agency wanted to initiate rule-making and the RPO said no?

Mr. AITKEN. Just as in the case of the memorandum that Director Panetta issued at the very beginning of the Clinton Administration, there is no requirement in the executive order nor was there any requirement in the original issuance of Executive Order 12866 for there to be disclosure requirements for the regulatory policy officer or even for the agency head and the agency head's activities regarding, say, the development of a plan.

Chairman MILLER. We have been joined by Mr. Baird. Mr. Baird, do you have any questions? I just gave back a minute and a half.

DIVISION OF POWER IN THE FEDERAL GOVERNMENT

Mr. BAIRD. I am interested in Mr. Aitken's comment just a second ago that it matters who is elected president. It surely does, but the Constitution puts legislative authority in the hands of the Congress, and if Congressional intent statute is usurped by the executive, is it your understanding that the role of the executive that they are to execute faithfully the laws enacted by the Congress or that the executive has the responsibility under the United States Constitution to usurp or circumvent those laws if they so choose?

Mr. AITKEN. Agencies must faithfully execute the laws that have been enacted. As a career government attorney, that has been my job, to ensure that agencies faithfully implement the statutes that have been enacted, and if Congress directs an agency to issue a regulation, the agency has to issue that regulation.

Mr. BAIRD. And when you say that it matters who is elected president, what does that mean?

Mr. AITKEN. Congress enacts statutes for very good reasons. It does not always specify in each last detail exactly what kind of regulations an agency should issue or has to issue. Therefore, because

there are complex issues, because there are policy issues that have to be resolved and perhaps because there was not enough consensus within Congress about which policies should be pursued, Congress has provided discretion to agencies in implementing those statutes, and that policy discretion, as the Supreme Court has recognized in the Chevron decision, does allow agencies to make policy judgments and those judgments appropriately can reflect the policies of the President, whoever the President may be.

Mr. BAIRD. If you are counseling somebody, one of these RPOs, about the process they use to formulate their decision, is it your counsel that they seek first to understand the executive position on a regulatory matter or that they seek first to understand the Congressional intent on the regulatory matter, and which of those is paramount if the two conflict?

Mr. AITKEN. The analysis would begin on any regulatory issue on how Congress has spoken on the issue. Every agency in order to undertake a rule-making needs authority, statutory authority, to carry out that rule-making. Congress sometimes provides permissive authority which the agency can or decide not to exercise or Congress in other instances mandates that an agency pursue a regulation and in some cases Congress mandates with great specificity the contours of that regulation. So the first issue for an agency would be, what has Congress said, has the Congress mandated that we issue a regulation or given us discretion.

Mr. BAIRD. But isn't the crux of part of what we are asking about here is, you just mentioned the first issue for an agency. One of the concerns is what if the RPO feels more beholden to the administration than to the Congressional intent, and if there is no way of tracking how that happens?

Mr. AITKEN. The executive branch has to comply faithfully with the laws that as passed by Congress.

Mr. BAIRD. How do signing statements fit into this? Does a signing statement by the executive somehow exculpate them from complying faithfully or unfaithfully, as the case may be, with Congressional intent? In other words, so you are saying on the one hand that the executive branch must comply with Congressional intent but this Administration has used signing statements at unprecedented levels. If a signing statement is made by the President, does the executive branch agency then comply with the statement that Congress has modified by a signing statement or as intended in the original text by the Congress?

Mr. AITKEN. I didn't come prepared to talk about signing statements and the relationship of signing statement on regulatory action.

Mr. BAIRD. Okay. I can understand that. But I will express concern that I would hope the agencies are complying with Congress, not with the intent as modified by a signing statement.

So your testimony to us is that you believe that the statutory language as enacted by the Congress takes precedent? Let me say it differently. Let us suppose a president were to suggest to his people that they just really don't like very much a law passed by the Congress and therefore what they would like to see is for an RPO to find any way around the law as passed by the Congress

rather than interpreting the intent of the Congress. Would that be an appropriate use of executive authority of an inappropriate use?

Mr. AITKEN. An agency must comply with the law. As the Supreme Court discussed in the 1984 decision on the Chevron case, Congress sometimes speaks very precisely on a particular issue. If that is the case, the agency must follow the Congressional direction. There are other times when Congress has spoken but has provided discretion to the agency on whether to act or on how to act.

Mr. BAIRD. Let us suppose we create a continuum and we say on the one end, Congress has spoken quite clearly. Would it be inappropriate for the President or one of his designees to say Congress has spoken clearly but we are still not happy with it, therefore, we would like this agency to find a way to circumvent it and not promulgate a regulation. Would that be inappropriate?

Chairman MILLER. I am sorry. If you could make that a short summary answer, we are now out of time and we do need to vote in a moment.

Mr. AITKEN. As the Supreme Court said in the Chevron case, if Congress has spoken on the precise question at issue, the agency must follow the Congressional direction.

Mr. BAIRD. And it would therefore be inappropriate? You are not quite answering my question. It would therefore be inappropriate for an executive officer to say to an agency, do not follow the Congress's direction?

Mr. Chairman, I know we have to vote, but if you have more questions, go ahead. I am sorry.

Chairman MILLER. I don't, not before voting anyway. Do you think you could answer that in a sentence?

Mr. BAIRD. Yes or no, would it be inappropriate for the President or his designees to tell an agency Congress had this intent, we would like you to try to find a way around that intent? Yes or no, would that be inappropriate?

Mr. AITKEN. It would not be appropriate if the Congress has spoken precisely on all the issues. Often it is the case, and it has been my experience over the years, including during the prior Administration, that Congress has provided policy discretion and so one of the issues that often comes up is, is there discretion within the statute that provides policy officials leeway to go one approach or to another approach, and that is often a discussion that arises regardless of who is the President.

Chairman MILLER. Mr. Rohrabacher needs to—can I come back after votes? And I want to offer my condolences and those of all the Members of the Committee on the loss of your brother. I know you need to get back to California to that funeral. Do you want to take some of the time?

Mr. ROHRABACHER. It usually takes us a couple of minutes to get to the Floor so I will make this a couple minutes worth of questions so we will have plenty of time to get to the floor.

So what we see here is an ominous trend. I mean, there is a pattern here. First of all, President Clinton got rid of all the U.S. attorneys immediately upon taking office. This president gets rid of seven of them later on but that trend—and then we see here a presidential executive order issued by President Clinton and nobody got to ask whether or not he had consulted outside people on

this and put them under oath and actually required all the documents and people to have good memories about who they talked to about this executive order, and now you have let it slip. You were there. Mr. Panetta issued an edict that the good-hearted public employees of the various departments and agencies couldn't issue any regulations. These political appointees actually got in place and were able to make the final decision. I smell a real problem here. I think that maybe we should have—there should have been hearings under Mr. Panetta's edict. Who did he discuss that with that we are cutting off the rights of those good-hearted honest public employees to set regulations down? You know, this is getting a little bit absurd and I would suggest that—now, let me ask you. You have had a lot of experience. You have been around longer than most people in this system. Do presidents usually try when they are marking out their policies, is it usually—isn't one of the considerations maintaining presidential authority and prerogatives?

Mr. AITKEN. That is correct.

Mr. ROHRABACHER. Now, that was President Clinton or President Bush? I mean, Democrats, Republicans, don't they all act that way?

Mr. AITKEN. That is correct.

Mr. ROHRABACHER. So when a president is sort of suggesting that he doesn't want to make all private deliberations available to Congress but we should discuss what the final decision is rather than the process he went through, isn't that a type of argument that Democrat and Republican presidents basically would all agree upon?

Mr. AITKEN. It has certainly been my experience that those presidents have over the years made that argument.

Mr. ROHRABACHER. And let me note that you have worked for Republican and Democrat presidents both, and there is no—you know, and you are saying that with experience and having been loyal to both presidents of both parties. And so I think that this hearing has been good in one respect. We really have had a serious discussion of some of the fundamental issues in terms of separation of powers of our country, and I think that that is important as to what you would expect employees to do and people to do in various departments and agencies, how it works out, and that has been a very good discussion. Trying to question the motives of people, how they have come to their conclusions in that discussion is not appropriate. We recognize that in the legislative branch. We have made it a rule of thumb that we do not question the motives of someone who is presenting an argument on the Floor of the House and that can actually—you can actually have your words taken down if you question the motives of someone. But we want to have an honest discussion of the issue at hand. That means you discuss the policy and not the process that someone has gone through in order to come to that policy conclusion. That type of goodwill I think is something that should be reflected in our overall democratic process. Unfortunately, when we get into this type of, why did you come to a decision and who did you talk to, and if you make any mistakes in remembering exactly how many conversations you had, if you forget one document, you are going to be prosecuted for it. I don't think that leads to—it doesn't benefit democracy and does

not benefit the people, and usually these things start happening as we are leading up to a major important election.

With that said, I thank you very much again for your service both to President Clinton and to President Bush and for giving us an understanding of how the process works from the inside.

Chairman MILLER. Mr. Aitken, you are dismissed. Thank you for being here.

I need to go vote. We all need to go vote. I could sprint back and then I would have to sprint back again after about 15 or 20 minutes of being here. Itt will be about an hour and we can go uninterrupted. What is the preference of the next panel? Consideration of whether I should sprint or not is not really the issue. Why don't I return in just a few minutes, take some testimony, then I will have to leave again. Thank you. The Committee stands in recess.

[Recess.]

Chairman MILLER. A quick note on the schedule. The full House is now finishing a vote. After that there will be a motion to recommit, followed by another 15-minute vote. So probably we will be able to go about 15 or 20 minutes and then I need to run back again. At that point I will be there for three additional votes and it will take me about maybe half an hour, maybe 20 minutes before I can get back. But it gives us a chance for all of you to begin and probably complete your initial testimony.

Mr. Strauss is the Betts Professor of Law at Columbia Law School. He is a nationally recognized expert in administrative law, constitutional law, legal method and legislation. He was a member of the faculty when I was a student. It his good fortune that I not today am not seeking vengeance for having embarrassed me in Socratic method as I never took his course as I could not imagine how I would ever need to know anything about administrative law. But I will note for Professor Strauss that I will be asking the questions today. Our next witness is Dr. Robert Hahn, the cofounder and executive director of the American Enterprise Institute's Brookings Joint Center for Regulatory Studies, which must feel sometimes like having Mr. Rohrabacher and I sit beside each other, which examines leading-edge issues in law, economics, law, regulation and antitrust. Dr. Gary Bass is the founder and executive director of OMB Watch and has worked extensively on federal budgetary program management, regulatory and information policy issues, and finally Dr. Richard Parker, a professor at the University of Connecticut and an expert on administrative law, environmental law, regulatory policy. He chaired the regulatory policy committee of the administrative law section of the ADA and has written on the use of cost-benefit analysis in OIRA.

As each of you know, your oral testimony is limited to five minutes but your entire written testimony will be placed in the record, and after the entire panel has given their testimony, the Members of the Committee, which probably will be me only, and I will do a series of five-minute blocks of questions. We will five minutes each to ask questions. So I will put all of you at ease as I did Mr. Aitken. I will now ask you all to stand. Do any of you have any objection to being sworn in? Is anyone represented by counsel today? Okay. Now that you are at ease, you may raise your right hand.

[Witnesses sworn]

Chairman MILLER. Thank you. We will begin with Professor Strauss. Excuse me. Let me amend that. Dr. Hahn is under a time restraint. Dr. Hahn, if you could testify first. Okay. Dr. Hahn will go second.

Professor Strauss.

Panel 2

STATEMENT OF MR. PETER L. STRAUSS, BETTS PROFESSOR OF LAW, COLUMBIA LAW SCHOOL

Mr. STRAUSS. I am sorry that your colleague had to leave because in his opening statement he made what seems to me the central point, at least from the perspective of my testimony, which is that it might be a good idea to ensure that they, and he was referring to the regulatory policy officers, are accountable to someone, and the issue that I mean to talk with you about is to whom they are accountable and what the Congressional stakes are in that.

The Constitution makes the President the overseer of all the varied duties that you give government agencies but equally clearly, it seems to me, it permits you to assign those duties to those agencies and not to the President, and for those duties, he is not the decider but rather the overseer of decisions that others make. The important point in my judgment is to preserve this distinction between presidential oversight, which is entirely appropriate and constitutionally commanded, and presidential decision. The assignment of decisional responsibility to others is a part of those laws to whose faithful execution the President must see, and when he fails to honor this rather subtle distinction, he fails in his constitutional responsibility to take care that the laws be faithfully executive.

The executive order we are discussing amends the longstanding Executive Order 12866 in several ways, and I want to focus on four language changes that in my view threaten the difficult but necessary balance between politicians and experts, between politics and law that characterizes agency rule-making. These are amendments to Section 4 and 6 concerning the regulatory plan, both of which diminish the effective control over regulatory decision by the agency head that you have put in charge of agency business and increase the President's control over regulatory outcomes, an increase that in my judgment requires Congressional authorization. You heard Professor Katzen, the previous administrator of OIRA, when she was here at the last hearing, talk to you about the step-by-step increase in presidential controls. Executive Order 13422 is another step in that direction, and from my perspective, a hazardous one.

The first change added these words to Section 4(c)(1) of the executive order applicable equally to executive and independent regulatory commissions: "Unless specifically authorized by the head of the agency, no rule-making shall commence nor be included in the plan without the approval of the agency's regulatory policy officer." This language purports to confer legal authority on the regulatory policy officer to control whether agency rule-making occurs subject

only to a specific countermand by the agency's head. Prior provisions of the order, President Clinton's order, merely hinted that denial of a place on the regulatory plan would preclude rule-making, and in my efforts to track this issue, I have never heard that it had happened. Your own provisions for the regulatory agenda in supriva are quite specific that presence on the regulatory agenda is not a condition of valid rule-making. Where did the President get the authority to impose this condition, much less to put it in the hands of a junior officer?

The second change I invite you to focus on subtracted these words from Section 4(c)(1): "The plan shall be approved personally by the agency head." So the agency head is no longer imagined as having general personal responsibility for his agency's important business. That is for the regulatory policy officer and the agency head just gets a veto, one whose exercise will doubtless be impeded by its specificity, visibility and vulnerability. When the regulatory plan was first rationalized, it was rationalized as an aid and it seemed to me an entirely appropriate aid to the political heads of administrative agencies requiring career staff to reveal their priorities and plans for rule-making to agency leadership in the same way that the dollar budget process does. So it sensibly injected the agency's political leadership into the picture before matters got set in bureaucratic concrete, but now that has been diverted to someone else.

The third change added this language to Section 6(a)(2): "Within 60 days of the date of this Executive Order, each agency head shall designate one of the agency's Presidential Appointees to be its Regulatory Policy Officer, advise OMB of such designation and annually update OMB on the status of this designation." The important elements to note here are that a presidential appointee is a person the President, not the agency head, gets to hire and fire, and the repeated references to OMB make clear who will be overseeing her performance. You may hear verbal promises that these presidential appointees will be of the kind that the Senate must confirm but of course the language doesn't say that, and even if it did, the fact would remain that the President, not the agency head, is in charge of the RPO's continuing tenure in the office.

The fourth change also in 6(a)(2) just confirms this pattern of displaced responsibility and division of authority. It subtracts the prior requirement of the section that the regulatory policy officer shall report to the agency head. Of course, the statute creating presidential appointees within an agency will itself embody some kind of reporting relationship but I think you can see how neatly this change echoes the others that I have mentioned. The order purports to confer legal authority on the junior authority in each agency whose identity must be coordinated with the White House to control the initiation of agency rule-making, and it seems to be intended its continuing processing within the agency. Conferring this kind of legal authority is Congress's business, not the President's, and it is authority I would urge you not to grant because it diffuses political authority within the agency that you generally entrust to the agency head. Congress, as well as the President, has political relationships with the agency head. While the President can cashier agency heads whose work he doesn't like, that comes

at a high political cost including having to get the Senate's agreement on a successor. As a well-connected friend told me, I personally watched two agency heads tell the President to pound sand. They wouldn't do what they were told and the President knew they had the political capital to win. Junior officers appointed under close White House supervision, knowing that they can be dismissed by the White House at any moment, won't have this political capital. There isn't as much chance that firing them will have political costs to the White House. They are not ever going to be telling the President or OIRA to go pound sand.

[The prepared statement of Mr. Strauss follows:]

PREPARED STATEMENT OF PETER L. STRAUSS

Thank you very much for inviting me to testify before you today. I am a scholar of administrative law, who has had the privilege of teaching that subject at Columbia Law School for the past 36 years and who for two years in the 1970's had the honor of serving as the first General Counsel of the Nuclear Regulatory Commission. I was later Chair of the ABA's Section of Administrative Law and Regulatory Practice, a consultant to the ABA's Coordinating Committee on Regulatory Reform, and long-time Chair of the Section's Rule-making Committee. My 1984 analysis of agency relations with the President won the Section's annual prize for scholarship. I have continued since then to write about separation of powers and, in particular, the President's constitutional relationship to the agencies on which Congress has conferred regulatory authority. Attached to this testimony is the current draft of my most recent writing on this subject, an essay to be published this summer by the *George Washington Law Review* entitled "Overseer or 'The Decider'—The President in Administrative Law." Here is its bottom line: Our Constitution very clearly makes the President the overseer and coordinator of all the varied duties the Congress creates for government agencies to perform. Yet our Constitution's text, with equal clarity, anticipates that Congress may and will assign duties to executive officials who are not the President. Respecting those duties, he is not "the decider," but the overseer of decisions by others. When the President fails to honor this admittedly subtle distinction, he fails in his constitutional responsibility to "take Care that the Laws be faithfully executed." The assignment of decisional responsibility to others is a part of the laws to whose faithful execution he must see. The important point, in my judgment, is to preserve this distinction between presidential oversight—entirely appropriate and constitutionally commanded—and presidential decision. For any agency's unique responsibilities, Congress's delegation makes the precise formulation of its priorities and plans the legal responsibility of the agency head. Honoring and protecting that responsibility is an important element of the President's obligation to assure that the laws are being faithfully executed. And the recent Executive Order amendments reflect a different view, in effect making the President not just the overseer, but the decider of these matters.

Our subject is Executive Order 13422, 72 Fed. Reg. 2763 (January 23, 2007), that amends the long standing Executive Order 12866, concerning regulatory planning and review. Others have addressed those elements of the order that reach guidance documents, another of its important elements, and that heighten the specificity of the analysis the order requires agencies to perform. I will leave those elements largely to them. Let me say only, as a long-time advocate of the proper use of guidance to help the public deal with agency regulatory standards, that I find the extension of the order to guidance documents possibly troubling only in its details. As a long-time supporter, as well, of the President's constitutional authority and wisdom in commanding regulatory analyses in connection with important rule-makings, I find that heightened specificity troubling only insofar as it may be administered to require agencies to decide matters on the basis of factors Congress has not authorized them to consider.

In these remarks I want to address two other aspects of the order, that I find particularly troubling. As Professor and former OIRA Administrator Sally Katzen testified to your committee two months ago, E.O. 13422 marks a distinct increase in the already significant degree of presidential control over regulatory outcomes, beyond that established by E.O. 12866, which in turn exceeded what had been done in its predecessor executive orders. Each step in a hazardous direction increases the hazard. In the aspects that concern me, E.O. 13422 takes a decisive step from President as overseer to President as decider. The President is not constitutionally entitled to

confer decisional authority on persons outside the White House, and Congress has conferred no such authority on him statutorily; but that, too, is what E.O. 13422 purports to do.

The first of the two aspects I wish to address amended the existing provisions respecting the agency's regulatory plan, and its regulatory planning officer, in ways that at the same time expand her authority, and seem to disconnect her from the agency head. Thus, the executive order amended §4(c)(1) of E.O. 12866 by adding

> *Unless specifically authorized by the head of the agency, no rule-making shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Officer,*

and subtracting a prior requirement that

> *The Plan shall be approved personally by the agency head*

The order also amended §6(a)(2) of E.O. 12866 by adding

> *Within 60 days of the date of this Executive order, each agency head shall designate one of the agency's Presidential Appointees to be its Regulatory Policy Officer, advise OMB of such designation, and annually update OMB on the status of this designation*

and by subtracting the previous requirement of the section that the Regulatory Policy Officer

> *shall report to the agency head*

The second element I wish to address added an entirely new idea to §6(a)(1) of the Executive Order, requiring that

> *In consultation with OIRA, each agency may also consider whether to utilize formal rule-making procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations.*

Both sets of changes, in my judgment, threaten to disturb the difficult but necessary balance between politicians and experts, between politics and law, that characterizes agency rule-making. The first threatens a diffusion of authority within agencies, and a dramatic increase in presidential control over regulatory outcomes, to an extent Congress has not authorized and in my judgment would have to authorize for this step to be valid. The second threatens redeployment of a discredited, remarkably expensive rule-making procedure that delivers substantial controls over the timing and cost of rule-making into the hands of private parties—notably, I fear, into the hands of those whose dangerous activities proposed regulations are intended to limit.

I. Presidential Control of Rule-making Agendas

When President Reagan elaborated the idea of a regulatory agenda in Executive Order 12498,[1] Christopher DeMuth, who had responsibilities for these issues in his administration, characterized it as essentially an aid to the political heads of administrative agencies—requiring career staff to reveal their priorities and plans for rule-making to agency leadership, just as the annual dollar budget process does, and consequently injecting the agency's political leadership into the picture before matters got set in bureaucratic concrete. Seen in this way, the measure supported Congress's assignments of responsibility—it is, after all, on the agency's political leadership alone that Congress's statutes confer the power to adopt rules. To judge by its own actions in measures like the *Regulatory Flexibility Act,* Congress like the private community was also attracted by the transparency and added opportunities for broad public participation early notice of rule-making efforts would provide.

President Clinton's Executive Order 12866 continued and in some ways strengthened this measure, requiring agencies to designate a regulatory policy officer who would coordinate general issues under the Executive Order—in effect be the agency's designated contact person for the OMB Office of Information and Regulatory Affairs (OIRA). While there were hints that this new measure might be used to effect presidential control over agency policy choices, years of paying fairly close attention to this question in my scholarship and professional associations have brought me no indication that this had happened. On specific issues of importance to him, as Dean Elena Kagan of Harvard has detailed, President Clinton through his domestic policy office—not OIRA—would issue directives to particular agencies on issues of importance to his program. President Bush's first head of OIRA, John Graham, initiated a practice of occasional "prompt letters" publicly directing agency attention

[1] A predecessor provision may be found in President Carter's E.O. 12044.

to matters that he concluded might warrant regulation. But a general centralization of actual control over regulatory agendas, so far as I could tell, was never effected. Until this order.

President Bush's order purports to confer authority on a junior officer in each agency, whose identity must be coordinated with OIRA, to control the initiation of agency rule-making and, it seems to be intended, its continued processing within the agency. It removes prior requirements that this junior officer "shall report to the agency head" and that the regulatory plan she is for the first time given explicit authority to control must be "approved personally by the agency head." I would have thought conferring this kind of authority and externally effecting such a striking reorganization of roles within an agency would be Congress's business, not something the President is authorized to do on his own. And if Congress were to ask my judgment about these steps I would call them an unwise diffusion of political authority within the agency, that Congress generally entrusts to the agency head. While legislation may permit the head to sub-delegate some of her authority to persons she trusts and will take responsibility for, Congress wisely has rarely if ever permitted sub-delegation of ultimate control over rule-making. It certainly would be unwise to confer such authority on persons who report to and are controlled by others outside the agency. Congress as well as the President has political relationships with the agency head. While the President has a formal capacity to discipline agency heads whose work displeases him, that capacity is sharply limited by the political costs of doing so—including the necessity of securing senatorial confirmation of a successor. As a well-connected friend of mine recently remarked,

> I personally have watched two agency heads tell the President to pound sand—they wouldn't do what they were told and the President knew they had the political capital to win.

Junior officers, given their responsibilities in a process under close White House supervision, knowing as "presidential appointees" that they can be dismissed at any moment, and lacking both this political capital and much prospect that their dismissal would have, in itself, political costs for the White House, are not ever going to be telling the President *or* OIRA to pound sand.

A number of gaps in the order make this problem, in my judgment, a lot worse.

> As remarked, the Clinton executive order reinforced ordinary agency hierarchy by providing in §6(a)(2) that the regulatory policy officer "shall report to the agency head." That language has been deleted. Now it is at least ambiguous to whom the RPO reports. Since the RPO must be a *presidential* appointee—that is, subject to presidential, not agency head dismissal—control over her tenure in this office, and in government service generally, has been moved to the White House. Anyone aware of the changes—the agency head, for example—will know that the prior mandatory relationship between RPO and agency head has been eliminated. One need only observe the ongoing drama over the firing of United States Attorneys to understand the potentials these changes open up.

Second, in requiring that the "policy officer" be a "presidential appointee," the amended order doesn't tell us what kind of presidential appointee—one who must also be confirmed by the Senate? One the President can name without need for confirmation? Perhaps a non-career officer in SES, whose appointment occurs only after White House clearance and with a presidentially-signed commission? If it is either of the latter, then the President has found his way around the constraints the Constitution insists upon, that people who exercise major authority in government can do so only with the Senate's blessing as well as his. Then it becomes even more apparent that the President has created a divided administration within each agency, with real power vested in a shadow officer who essentially answers only to him. As my friend also remarked, this would be "disastrous."

> First as a practical matter it takes regulatory power away from the head of the agency where Congress has vested it. Second, it continues the political accretion of power in the bureaucracy of the White House, away from public scrutiny. But, the worst part from my vantage point is that it treats the agency as a conquered province—the career staff is explicitly told it is distrusted and is not to make recommendations to the agency head but to the White House's political officers. That in turn destroys communication between the staff and the political level of the agency. And, the agency is quite ineffective when that happens.

Third, it is unclear to what extent the new controls extend to the independent regulatory commissions. Section 4's language, including the requirement that "Unless specifically authorized by the head of the agency, no rule-making shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy

Officer," is explicitly applicable to independent regulatory commissions. Section 6, that defines the regulatory policy officer's appointment, is not. As a legal requirement of agencies Congress has chosen to constitute as independent regulatory commissions, this is truly extraordinary.

The final gap I want to note for you, one of signal importance in my judgment, concerns political access. Among the elements that have made the Executive Order regime acceptable to Congress, and I might add to much of the academic community, are the commitments it contains to a professionalized, unusually transparent and apolitical administration. Oral contacts with outside interests are limited to OIRA's senate-confirmed Administrator or his particular designee; agencies attend any meetings with outsiders; written communications from outsiders are also logged; and all of this information is publicly disclosed. My understanding is that Congress has properly insisted on these elements of transparency, as a condition of its acceptance of this generally valuable regime. The OIRA website, within a generally closed White House environment, has been a remarkable monument to the worth of this insistence.[2] The professional qualities, too, of OIRA's staff, and the striking qualities of its leadership over time, have offered reassurance. Notice that none of these constraints are made applicable to the Regulatory Policy Officer or his office. It can be open season there.

So the President has attempted to do by executive order something that, in my judgment, can only be done by statute. Moreover, in doing so he threatens excessive politicization of agency rule-making, the subversion of a public process by back-corridor arrangements, and compromising the lines of authority Congress has created. That these officers will, in practice, be answerable chiefly to him is underscored by President Bush's subtractions from Executive Order 12866, as well as his additions to it. Their conversations with him, his lieutenants, and any political friends he may send their way will be invisible to us.

You will likely hear from the other side that the President is, after all, our chief executive, that our Constitution embodies the judgment that we should have a unitary executive, and so even if the result were to convert agency judgments about rule-making into presidential judgments, that would only be accomplishing what the Constitution commands. This is the subject of the writing I have attached to this testimony. In my judgment it is not only an erroneous argument, but one dangerous to our democracy. The President is commander in chief of the armed forces, but not of domestic government. In domestic government, the Constitution is explicit that Congress may create duties for Heads of Departments—that is, it is in the heads of departments that duties lie, and the President's prerogatives are only to consult with them about their performance of those duties, and to replace them with senatorial approval when their performance of those duties of theirs persuades him that he must do so. This allocation is terribly important to our preservation of the rule of law in this country. The heads of departments the President appoints and the Senate confirms must understand that their responsibility is to decide—after appropriate consultation to be sure—and not simply to obey. We cannot afford to see all the power of government over the many elements of the national economy concentrated in one office.

Professor Peter Shane, a highly respected scholar of the presidency and a former lawyer in the Office of Legal Counsel, put the matter this way in a recent discussion of President Bush's use of signing statements, which I know is not our subject today.

> The Bush Administration has operated until recently in tandem—can there be a three-part tandem?—with Republican Congresses and a Supreme Court highly deferential to executive power. . .. It has not only insisted, in theory, on a robust constitutional entitlement to operate free of legislative or judicial accountability, but it has largely gotten away with this stance. And that success—

[2] This is not the setting to explore the accounts I am beginning to hear of increasing, and in my judgment, regrettable, politicization and transparency violations in OIRA functioning—for example, deliberate holding back the clock on formal submission of agency proposals to OIRA, so that negotiations and "adjustments" can be complete before the transparency provisions of E.O. 12866 kick in. See United States General Accounting Office, Report to Congressional Requesters," RULE-MAKING, OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews," GAO–03–929, September 2003, pp. 47–48. When evidence of OIRA changes has been available, it has been available to assist reviewing courts in determining whether agencies have themselves reached the decisions statutes commit to their responsibility, and done so only on consideration of the statutorily relevant factors. See Riverkeeper, Inc. v. EPA, No. 04–6692–ag(L), 2007 U.S. App. LEXIS 1642 (2d Cir. Jan, 25, 2007), where the published documents showed 58 "major" changes having been made "at the suggestion or recommendation" of OIRA at the proposal stage, and 95 "major" changes made "at the suggestion or recommendation" of OIRA in the rule as finally promulgated.

> the Administration's unusual capacity to resist answering to Congress and the courts—has fed, in turn, its sense of principled entitlement, its theory that the Constitution envisions a Presidency answerable, in large measure, to no one.
>
> Critics of the Administration have not infrequently charged that the Administration's unilateralism is antagonistic to the rule of law. After all, the ideal of a "government of laws, not of men" seems conspicuously at odds with a President's expansive claims of plenary authority. But no sane President claims to be above the law and, indeed, President Bush takes pains repeatedly to defend his controversial actions as legal, including the widespread warrantless electronic surveillance of Americans, the incarceration of U.S. citizens as enemy combatants, and the intense interrogation of detainees in Iraq and Afghanistan. I doubt that President Bush thinks himself antagonistic to the rule of law; he just has a different idea of what the rule of law consists of. But what the Administration seems to believe in is a version of the "rule of law" as formalism. It is the rule of law reduced to "law as rules." Under the Bush Administration's conception of the rule of law, Americans enjoy a "government of laws" so long as executive officials can point to some formal source of legal authority for their acts, even if no institution outside the executive is entitled to test the consistency of those acts with the source of legal authority cited. . ..
>
> The Bush signing statements, like the doctrines they advocate, are a rebuke to the idea of the rule of law as norms or process. They are a testament to the rule of law as law by rules, preferably rules of the President's own imagination.

This executive order is cut from the same cloth.

What might Congress do about this? This looks like a simple affront to two of Congress's responsibilities—to confer organization and authority on elements of government by enacting statutes, and to approve (in the Senate) all appointments to high office (thus creating one of the Constitution's many checks on unilateral authority in any branch). Legislative change here, though, would likely encounter a presidential veto. Can you find a way to avoid that? There remains the power of the purse. While the use of "do not spend" riders in appropriations measures has often been criticized, perhaps this is a setting in which such a rider would be appropriate, attached to a budget the President will find himself compelled to sign. Why should Congress tolerate the expenditure of government funds to pay the salary of one whose powers it has not authorized, and whose functioning can prove destructive of the public institutions it has worked to create?

II. Outsider Control of Rule-making

I can be much briefer in addressing the provision of the executive order that invites agencies to "consider whether to utilize formal rule-making procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations," "in consultation with OIRA." This is permissively worded, but one must wonder how permissive its implementation will be. And what you should note are the differences between "formal rule-making procedures under 5 U.S.C. 556 and 557" and the notice-and-comment procedures agencies generally employ. On-the-record rule-making occurs under the aegis of an administrative law judge, a person trained in trials not policy-setting; notice and comment rule-making is coordinated by the agency's policy staff. Even more important, on-the-record rule-making confers on participants the kinds of rights parties to trials have—rights to put on witnesses, engage in cross-examination, and in other ways slow rule-making down and add to its internal costs. It is, simply, the delivery of the henhouse to the foxes.

Experience with on-the-record rule-making led to its virtual abandonment decades ago, and for good reason. Those familiar with the process have recognized for 40+ years that it is simply too clumsy to work except in very isolated instances. In its 1973 judgment in *U.S. v. Florida East Coast Rwy,* 410 U.S. 224, the Supreme Court essentially ruled that agencies did not need to use it in the absence of the clearest of statutory instructions. Congress hasn't been giving those instructions, and agencies haven't been using that process ever since, and for good reason. Experience has taught us that the use of formal rule-making is cumbersome and out of all proportion to its benefits because trial-type hearings are poorly suited for determinations that turn on policy judgments, and too subject to unwarranted extension and complication by the participant parties. Why, then, revive it now? Just to help one's friends slow things down—to throw a good dose of sand into the gears of rule-making?

Thank you for the opportunity to address you today. I would be happy to answer any questions you might have.

BIOGRAPHY FOR PETER L. STRAUSS

Peter L. Strauss, the Betts Professor of Law at Columbia Law School, has taught courses in Administrative Law, Constitutional Law, Legal Methods, and Legislation since 1971. A graduate of Harvard College and Yale Law School, he previously clerked for the Hon. David L. Bazelon and William J. Brennan, Jr., taught criminal law at the national university of Ethiopia, and spent three years as an attorney in the Office of the Solicitor General, briefing and arguing cases before the United States Supreme Court. During 1975–77, Professor Strauss was on leave from Columbia as the first General Counsel of the United States Nuclear Regulatory Commission. His published works include *Administrative Justice in the United States* (1989) and 2002 *Gellhom's & Byse's Administrative Law: Cases and Comments* (most recently, 2003, with Rakoff and Farina), *Legal Methods: Understanding and Using Cases and Statutes* (2005), *Legislation: Understanding and Using Statutes* (2006) and *Administrative Law Stories* (Ed., 2006) and numerous law review articles, generally focusing on issues of rule-making, separation of powers, and statutory interpretation. In 1987 the Section of Administrative Law and Regulatory Practice of the American Bar Association gave Professor Strauss its third annual award for distinguished scholarship in administrative law. In 1992–93, he served as Chair of the Section. He has twice been Vice Dean at Columbia. Professor Strauss has visited at Harvard and NYU, and lectured widely on American administrative law abroad, including programs in Argentina, Belarus, Brazil, China, Germany, Italy, Japan, the Netherlands, Mexico, Turkey and Venezuela. He is founding editor of the Social Science Research Network's Administrative Law Abstracts, and a member of the board of the Center for Computer Assisted Legal Instruction.

Chairman MILLER. Thank you.

Dr. Hahn.

STATEMENT OF DR. ROBERT W. HAHN, EXECUTIVE DIRECTOR, AEI–BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

Dr. HAHN. Thank you, Chairman Miller. I am going to try to focus on some of the substantive issues in the executive orders. My coauthor, Bob Litan, and I have studied and written about regulatory issues for, dare I say, more than two decades from an economic perspective, and it is from that perspective that I approach the analysis of the President's new executive order.

Our bottom line is that the new order is not as revolutionary or far-reaching as the critics make it out to be, and indeed the actual requirements or additional requirements of this order are modest. I would like to make the following three points.

First, expanding the executive order to consider guidance is a positive step. Second, the changes regarding regulation are not likely to substantially increase an agency's analytical burden. And third, the expansion of presidential influence over major regulatory policies is on balance a good thing and will serve to enhance accountability.

First, treating guidance like regulation is a good thing. The new Bush executive order includes regulatory guidance when its impact is likely to be significant. We don't know the impact of most guidance, but we do know that regulatory agencies issue a lot of it. For example, the FDA has an online list of over 1,500 guidance documents that are currently in use. The new Bush order requires that each agency evaluate the need for and consequences of guidance, helping to ensure that it is reasonable. I don't think that is a lot to ask for. Some critics argue that oversight is not needed because guidance is non-binding. This is simply wrong. Consider a situation where an agency says that it is acceptable to use blue paint to comply with the regulation, but is silent on whether yellow paint might be used. I would imagine that you would see a lot more firms com-

plying with that regulation using blue paint rather than yellow paint. That to me looks a lot like a regulation, and to borrow a phrase, if it looks like a regulation and quacks like regulation, then I think it should be treated like a regulation.

Our second point is that the executive order changes, regarding regulation, are not likely to substantially increase an agency's analytical burden. The new E.O. adds some requirements for new regulation. For example, some critics have complained about the requirement that an agency provide a written rationale explaining why it is regulating, but this isn't really a new thing, as you heard earlier. The only real difference between the Bush order and President Clinton's order is that the Bush order specifically requires that rationale to be in writing. In general, the requirement of a rationale, which was first added by President Clinton, is important and should be applicable to all regulation and guidance. If agencies don't have a good economic rationale for regulation, you and the public deserve to know that. Furthermore, the Bush order stops short of requiring that the agency specify a clear economic rationale. It simply needs to specify a rationale, any rationale.

Third, the expansion of presidential influence is likely to promote greater accountability and better economic policy. I am running out of time so I will be brief here. The basic idea is one that you mentioned earlier, that unelected government civil servants are not necessarily in the best position to be making tough policy choices. Indeed, they may suffer from a kind of tunnel vision as Justice Breyer noted in his book, Breaking the Vicious Circle.

If I were to have any complaint about the President's executive order, it is that it does not go far enough. In particular, it excludes independent agencies like the Federal Trade Commission, the Federal Communications Commission, and FERC from review. Professor Cass Sunstein and I have argued in a law review paper that these independent agencies should be subject to regulatory review. In addition, I would also suggest subjecting significant guidance documents to a broadly based benefit-cost test. This would give regulators and the public a better understanding of the likely economic impacts of guidance and could also improve guidance.

In conclusion, we think the new executive order on regulation represents a modest improvement over previous orders. It is also consistent with the global trend towards featuring a more prominent role for economic analysis in informing regulatory decisions.

Thank you, and I would be happy to take your questions.

[The prepared statement of Dr. Hahn follows:]

PREPARED STATEMENT OF ROBERT W. HAHN

Evaluating the New Executive Order on Regulation

ROBERT W. HAHN AND ROBERT E. LITAN[1]

Executive Summary

In 2007, President Bush amended President Clinton's executive order on government regulation, making changes that could have far-reaching consequences for how

[1] Robert W. Hahn and Robert E. Litan are the directors of the AEI-Brookings Joint Center for Regulatory Studies. This testimony builds on our piece in the Economists' Voice. The authors would like to thank Caroline Cecot and Molly Wells for excellent research assistance. The views

the government weighs the costs and benefits of regulatory activity. Although the new Bush executive order would impose greater requirements on regulatory agencies than are currently imposed, we think the benefits are likely to exceed the costs. We argue that the new– executive order should have included independent regulatory agencies, such as the Federal Communications Commission, in addition to executive regulatory agencies.

I. Introduction

We are pleased to appear before this subcommittee to present our views on the recent executive order on regulation. We have studied and written about regulatory institutions for more than two decades. About a decade ago, we organized a cooperative effort between the American Enterprise Institute and the Brookings Institution to study regulation. The result was the AEI–Brookings Joint Center for Regulatory Studies.[2]

A primary objective of the center is to hold lawmakers and regulators more accountable by providing thoughtful, objective analysis of existing regulatory programs and new regulatory proposals. The Joint Center has been at the forefront of outlining principles for improving regulation, enhancing economic welfare, and promoting regulatory accountability.[3]

Our testimony analyzes the new executive order on regulation. In 2007, President Bush amended President Clinton's executive order on government regulation, making changes that could have far-reaching consequences for how the government weighs the costs and benefits of regulatory activity.[4] We argue that the changes in the order are modest and that the new order is generally an improvement. Specifically, we believe that expanding the executive order to consider guidance is a positive step; the changes regarding regulation are not likely to substantially increase an agency's analytical burden; and, the expansion of presidential influence over major regulatory policies will serve to enhance accountability.[5]

II. Treating Guidance More Like Regulation

The new Bush order adds to the old Clinton order in three key ways. First, instead of focusing primarily on federal regulations that are likely to cost hundreds of billions annually, the Bush order also focuses on regulatory "guidance" when its impact is likely to be significant. Guidance is similar to regulation because it presents an agency's interpretation or policy on a particular regulatory or technical issue, but it is usually non-binding.[6] For example, the Environmental Protection Agency has issued guidance on the interpretation of waste management activities, and also on some reporting requirements under the *Community Right-to-Know Act*.[7]

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expressed here represent those of the authors and do not necessarily reflect those of the institutions with which they are affiliated.

[2] All publications of the AEI–Brookings Joint Center can be found at *http://www.aei.brookings.org.*

[3] *See* Arrow et al. (1996).

[4] *See* Exec. Order 13,422, 72 Fed. Reg. 2763 (2007) [hereinafter Exec. Order 13,422]. Previously, President Bush only made minor changes to Exec. Order 12,866, such as transferring the roles assigned to the Vice President to the OMB Director or Chief of Staff. See Exec. Order 12,866, 58 Fed. Reg. 51,735 (1993) [hereinafter Exec. Order 12,866]; Exec. Order 13,258, 67 Fed. Reg. 9385 (2002).

[5] For a more pessimistic view of Exec. Order 13,422, see Sally Katzen, *Amending Executive Order 12866: Good Governance or Regulatory Usurpation?,* Testimony 07–01: AEI–Brookings Joint Center for Regulatory Studies (2007) (focusing on the restrictions of agency discretion) and Peter L. Strauss, *Testimony of Peter L. Strauss Concerning President Bush's Recent Amendments to Executive Order 12866,* Testimony 07–02: AEI–Brookings Joint Center for Regulatory Studies (2007) (discussing possible separation of powers concerns). *See also* Robert Pear, Bush Directive Increases Sway on Regulation, *N.Y. TIMES,* January 30, 2007; Cindy Skrzycki, Bush Order Limits Agencies' 'Guidance', *WASH. POST,* January 30, 2007, at D01.

[6] There are certain kinds of guidance that may be considered binding. *See* Robert A. Anthony, Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like: Should Federal Agencies Use Them to Bind the Public?, 41 *DUKE L. J.* 1311, 1311–84 (1992). OMB makes it clear that guidance cannot impose a legally binding requirement. *See* Office of Management and Budget, Final Bulletin for Agency Good Guidance Practices, Bulletin No. 07–02: Executive Office of the President (2007) [hereinafter OMB, Guidance]. *See* M. Elizabeth Magill, Agency Choice of Policy-making Form, 71 *U. CHI. L. REV.* 1383, 1383–1447 (2004) for a discussion of the kinds of regulatory tools statutes and case law make available to agencies, and why agencies select certain tools such as adopting a rule, bringing a case to court, or issuing guidance.

[7] *See* Environmental Protection Agency, *Interpretations of Waste Management Activities: Recycling, Combustion for Energy Recovery,* Treatment for Destruction, Waste Stabilization and Release, Office of Pollution Prevention and Toxics (1999); Environmental Protection Agency, *Emergency Planning and Community Right-to-Know Act-Section 313: Guidance for Reporting Releases and Other Waste Management Quantities of Toxic Chemicals: Lead and Lead Compounds.* EPA

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No one actually knows the real impact of most guidance, but it could be substantial. We do know that regulatory agencies issue significant amounts of guidance. The U.S. Food and Drug Administration has a list of over 1,500 guidance documents that are currently in use.[8] Previously, agencies could issue guidance documents in lieu of regulations in order to circumvent the requirements of regulatory review required by executive orders used by President Reagan, the first President Bush, and President Clinton.[9]

The new Bush order will change the way guidance is handled by requiring that each agency evaluate the need for and consequences of the guidance, helping to ensure that it is reasonable. The specific requirements are modest, such as making sure that the guidance is consistent with applicable law, compatible with other regulations and guidance documents, and simple and easy to understand. Before issuing a significant guidance document, which could have an annual effect on the economy of $100 million or more, the agency must notify OMB's regulatory office and submit the draft with an explanation of why guidance is needed, but it is not required to do a full benefit-cost analysis. OMB can then select guidance that could benefit from regulatory review.

Critics suggest that applying some of the same standards to federal guidance as now apply to regulation will allow big business to exert more control over the process, either by delaying the issuance of guidance or changing the guidance to meet its needs. The critics might be right in some instances. In general, however, forcing guidance to be consistent, compatible, and understandable is appropriate.[10]

Interestingly, applying the new standards to guidance could serve to slow efforts by an administration interested in reducing burdens on business. If, for example a regulatory agency were captured by business interests, but guidance had to be approved by OMB, there would at least be some chance that OMB might pinpoint guidance that did not help the general public, or at least slow the rate at which such guidance is issued.[11]

Some critics also contend that the new executive order could impose undue analytical burdens on regulatory agencies. For example, some argue that oversight is not needed because much guidance is non-binding.[12]

The critics raise an important point, the solution to which is to make sure OMB's regulatory office implements its new oversight responsibilities wisely. If guidance is truly non-binding in an economic sense—say, because it does not affect firm behavior—then there is little reason to spend time analyzing it. However, there are cases when guidance may be non-binding in a legal sense, but could affect behavior.[13] Consider a situation where an agency says that it is acceptable to use blue paint to comply with a regulation, but is silent on whether using yellow paint is acceptable. This guidance could have the effect of encouraging firms to use blue paint more than they otherwise would, even though there is not a formal requirement to use it.

Still, we are concerned that the process could slow or stop the issuance of some guidance that serves a useful social purpose. One possible example is guidance from the Food and Drug Administration, which already has good guidance standards and

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260–B–01–027: Office of Environmental Information (2001). More Environmental guidance documents can be found at *http://www.epa.gov/epahome/search.html.*

[8] For the list of all Food and Drug Administration guidance documents currently in use, see Notice, *Annual Comprehensive List of Guidance Documents at the Food and Drug Administration,* 70(3) Fed. Reg. 824–913 (2005), available at *http://www.fda.gov/OHRMS/DOCKETS/98fr/05-155.htm.*

[9] *See* OMB, *Guidance, supra* note 5 at 3.

[10] The American Bar Association, for example, has issued statements calling for public comment on significant "nonlegislative rule(s)" and for availability of these documents on agencies' websites. *See* American Bar Association, *Rule-making Procedures for Non-Legislative Rules,* A.B.A. (1993); American Bar Association, *Recommendation on Federal Agency Web Pages,* A.B.A. (2001). The American Bar Association confirms this in a draft letter regarding the amendments to Exec. Order 12,866, available at *http://www.abanet.org/adminlaw/midyear/2007/Tab4Cletter12866.pdf* [hereinafter A.B.A., Draft].

[11] Those who believe that the OMB review process is captured by business are unlikely to be persuaded by this argument. We believe OMB regulatory review tends to focus more on economic welfare of producers and consumers. That is, in part, because the executive orders focus on economic efficiency, which counts benefits and costs to workers, consumers, and owners of capital.

[12] Non-binding means that firms and other affected parties are not required to do anything specific. See OMB, *Guidance, supra* note 5 at 9 for this concern, raised by several commentators on the proposed Bulletin.

[13] See OMB, *Guidance, supra* note 5 at 9–10 (describing how guidance documents could have "coercive effects" or lead to a change in behavior).

posts guidance on its web site.[14] It appears that a significant amount of guidance issued by this agency can reduce the overall regulatory burden by more clearly articulating government policy toward getting approval of drugs or medical devices. Such guidance would likely pass a benefit-cost test if its primary effect is to reduce regulatory uncertainty without sacrificing the social goal, which in this case could be assuring that a new drug is reasonably safe and effective. Determining the appropriate level of review for the guidance review process will entail tradeoffs between limiting guidance that improves economic welfare and discouraging guidance that reduces economic welfare.

As OMB learns more about the likely effect of different types of guidance, it should tailor its analytical reporting requirements accordingly. In addition, it should take great care in implementing a formal rule-making for particular guidance because this process is time consuming and relatively costly.[15] Because OMB's regulatory office has a very small staff for reviewing regulation and guidance, it has some incentive not to impose burdensome reporting requirements on agencies because then it would be expected to review these reports.

III. New Requirements for Regulation

The new order also adds some requirements for regulation. One feature, highlighted in the press, is that the Bush order requires an agency to provide a written rationale explaining why it is regulating. The only real difference between the Bush order and the Clinton order is that the Bush order specifically requires that the rationale be in writing. A careful reading of the Bush order suggests that a rationale for significant guidance should also be provided as a brief explanation for OMB.

This requirement is important, and should be included for all regulation and guidance. Most economists would agree that the government should not consider regulating unless there is a clear market failure being addressed, such as pollution, monopoly, or lack of good information. The Bush order stops short of requiring that the agency specify a market failure, per se. The agency simply needs to provide a reason for regulating. Regulatory agencies owe the citizenry at least that much before they decide to regulate.[16]

Another feature of the regulatory proposal that has been criticized in the press is the requirement that agencies provide aggregate annual costs and benefits of all regulatory activity on the agency's plan. This requirement should not add substantially to the analytical burden of regulatory agencies because they already must present anticipated costs and benefits of individual regulations on the plan.[17] There

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[14] *See* Notice, *The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents,* 62 Fed. Reg. 8961 (1997). The good guidance practices have some of the same features as OMB, *Guidance, supra* note 5, including absence of mandatory language, advance notice and opportunity for public comment on some guidance, and posting of guidance on the Internet. Guidance from the Food and Drug Administration is available at *http://www.fda.gov/opacom/morechoices/industry/guidedc.htm.* The Biologics Consulting Group also maintains a database of the Food and Drug Administration's guidance documents, available at *http://www.biologicsconsulting.com/guidancedocuments_all.htm.*

[15] The American Bar Association expressed concern about the new provision to Exec. Order 13,422, *supra* note 3, reminding agencies to consider using formal rule-making for complex determinations. *See* A.B.A., *Draft, supra* note 9. We, however, agree with the view expressed by Paul R. Noe, *Changes to OMB Regulatory Review by Executive Order 13422,* Testimony 07–04: AEI–Brookings Joint Center for Regulatory Studies (2007). Noe, *supra,* believes that because agencies always had the option to consider formal rule-making, this provision is not likely to change anything.

[16] Professor Sally Katzen, *supra* note 4, former head of regulatory review at OMB, argues, "By giving special emphasis to market failures as the source of a problem warranting a new regulation, the Administration is saying that not all problems are equally deserving of attention; those caused by market failures are in a favored class and possibly the only class warranting new regulations." *See* Katzen, *supra* note 4. We think it is good for government generally to focus on market failures because too often government policies result in serious economic inefficiencies. *See* CLIFFORD WINSTON, GOVERNMENT FAILURE VERSUS MARKET FAILURE: MICROECONOMICS POLICY RESEARCH AND GOVERNMENT PERFORMANCE (AEI–Brookings Joint Center for Regulatory Studies 2006). Katzen brings up the example of civil rights. We think some civil rights legislation could have been justified on the basis of market failure arguments. Nonetheless, the Bush EO clearly allows for the agency to provide a rationale other than market failure. "Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted" [emphasis added]. *See* Exec. Order 13,422, *supra* note 3.

[17] Exec. Order 12,866, *supra* note 3, already required that the agency report the most significant rules on a "Regulatory Plan," along with each rule's anticipated benefits and costs. Exec.

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is value in having an estimate of the annual regulatory cost, much in the same way that government provides an annual budget estimate. We would also add that, where possible, the annual regulatory cost should be compared with the annual regulatory benefit.

III. Expanding Presidential Influence

The third change in the Bush executive order is to require affected regulatory agencies to designate a presidential appointee as the regulatory policy officer. The regulatory policy office would then need to approve a specific regulation before it could be included in the agency's annual regulatory plan of the important regulations it expects to issue.

This change could be very important. Critics believe that it would politicize the process by taking away some discretion from civil servants. We agree with the critics, but think this is ultimately a good thing. The benefits are similar to the benefits of regulatory oversight in general. First, as Justice Breyer has noted, civil servants in some regulatory agencies may tend to have tunnel vision, and fail to consider the broader impacts of their regulatory proposals.[18] Second, requiring that a presidential appointee in a policy office approve regulations increases the chances that the regulations will consider costs and benefits because such balancing is more likely to be consistent with the President's agenda than an agency's agenda. Third, this change will hold the President more accountable for regulatory policies that his administration selects.[19] Of course, the particular person the President appoints could skew the process away or towards the balancing of costs and benefits, but we think the President should have that choice because voters can hold him accountable for his policies.

IV. New Executive Order Should Have Been More Ambitious

If we have any complaint about the President's executive order, it is that it does not go far enough. In particular, it excludes a whole group of regulatory agencies from review—the "independent" regulatory agencies like the Federal Trade Commission, the Federal Communications Commission, and the Federal Energy Regulatory Commission—that play a critical role in a number of areas ranging from telecommunications to energy.

We would suggest bringing these independent agencies under the executive order's umbrella.[20] This change would hold a wider range of regulators more accountable for the costs and benefits of their policies and hopefully lead to more efficient policies across the board. It is still an open question as to whether the President has the legal authority to make this change; if the President does not, then Congress should give this general authority to the President directly.[21]

In addition, we would suggest subjecting significant guidance documents to the same requirements as significant regulations—namely benefit-cost analysis and a broadly based benefit-cost test. This would give regulators and the public a better understanding of the likely economic impacts of guidance, and it could also improve actual guidance.

Although the new Bush executive order would impose greater requirements on regulatory agencies than are currently imposed, we think the benefits are likely to exceed its costs, but a lot will depend on how it is implemented. The new executive order is also consistent with a global trend toward featuring a more prominent role for economic analysis in informing regulatory decisions.

BIOGRAPHY FOR ROBERT W. HAHN

Robert Hahn is co-founder and Executive Director of the American Enterprise Institute-Brookings Joint Center, which examines cutting-edge issues in law and economics, regulation and antitrust. Previously, he worked for the Council of Economic

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Order 13,422, *supra* note 3, only asks that agencies sum the estimated benefits and costs of the regulations, which is a way of enhancing transparency. *See* Steven D. Aitken, *Statement of Steven D. Aitken, Acting Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget before the Subcommittee on Commercial and Administrative Law of the Committee on the Judiciary, United States House of Representatives* (2007). Katzen, *supra* note 4, believes that this estimate will be meaningless and should not be included.

[18] *See* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (Harvard University Press 1993).

[19] *See* Strauss, *supra* note 4, for objections to this view on the grounds of the need for separation of powers.

[20] *See* Robert W. Hahn & Cass R. Sunstein, A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis, 150 *U. OF PENN. L. REV.* 1489 (2002).

[21] *See* Strauss, *supra* note 4, for an opposing view.

Advisers, where he helped design the innovative market-based approach for reducing acid rain. Dr. Hahn also has served on the faculties of Harvard University and Carnegie Mellon University. He frequently contributes to leading scholarly journals and general-interest periodicals, including the *American Economic Review, Yale Law Journal, Science,* and the *New York Times.* Dr. Hahn is the author of *Reviving Regulatory Reform: A Global Perspective* (AEI–Brookings) and several other books. He has served as a consultant to governments and business on a variety of economic issues. In addition, Dr. Hahn is co-founder of the Community Preparatory School—an inner-city middle school in Providence, Rhode Island, that provides opportunities for disadvantaged youth to achieve their full potential.

Chairman MILLER. Thank you, and I think now I need to go vote. Dr. Hahn, I understand you probably cannot be here when I get back but I will be gone for probably around 20 minutes, and I apologize. It is simply the schedule we are on. There is only so much we can do about it. But I will be back as quickly as I can. Thank you, and we will be in recess.

[Recess.]

Chairman MILLER. We will resume. Dr. Gary Bass will testify next.

Dr. Bass.

STATEMENT OF DR. GARY D. BASS, EXECUTIVE DIRECTOR, OMB WATCH

Dr. BASS. I appreciate the opportunity to testify and for your running back and forth. It is wonderful of you.

Let me start by just posing a question for the record, and that is, if those people who are so supportive of the executive order changes say that it is so minimal, then what was the purpose of doing the changes in the executive order? And so I have sort of a rhetorical question on that point. If it really was nothing, then why so late into this Administration was any change made? I also want to just open by indicating that if Professor Strauss raises constitutional questions about the executive order, you can bank on it. I mean, that is a critically important point, and even if there aren't constitutional problems, this is bad policy. So let me start with the whole point that no one has said the objective should be to actually get rid of this executive order, and whether Congress chooses to directly approach that or whether it chooses through the power of the purse to withhold funding for the implementation of components of it, that is the strongest recommendation that I could possibly make. Now, within that context, I think that in the immediate side, transparency and accountability, as you, Mr. Chairman, have mentioned, is essential. So let us turn to transparency as a theme.

First of all, let us talk about transparency in the entire regulatory process overall. At best, I would describe it as walking into a dark room and the government handing you a flashlight when you could flip a switch and have floodlights instead. It is not very transparent, is the point I would make. And now you add in the enhanced powers that Professor Strauss talked about of the regulatory policy officer where there is no transparency, you are totally in the dark, not even a flashlight. So if Congressman Rohrabacher and Mr. Aitken believe in transparency, it seems to me one place to start is to really provide some transparency for the entire regulatory process. Now, I could spend some moments about the OIRA power and what has happened as well as the power that would exist because of the RPO at the agencies, but instead of spending

my time on that, I want to directly talk about specific recommendations for transparency.

One sentence before that though that I want to mention and that is, most of the discussion about OIRA's power has been in the context of the executive order itself, what they do during the regulatory review. That is the formal review process. What is striking is the informal part of it, meaning what I would call pre-rule-making. The dialog that occurs between OIRA or the White House and the agencies before the formal process ever kicks in is critical to any kind of public accountability, and right now there is no transparency on that process at all, and in fact, by the changes in the executive order, we have enhanced more power in that pre-rule-making stage and yet no transparency.

So let me turn to recommendations. First, let me do it in two ways. One is for the agency itself and then turn to reviewing authorities such as OIRA or Small Business Administration, and I will only use five under each because I was always told you can count up and then still pound your hand and still advocate for it all at the same time. So one, at the agency level, it is essential to have disclosure of who these new RPOs will be—or not new, the new enhanced power, but the political appointees could be new—who they are, what their responsibilities are, what the procedure would be within the agency. For example, when does a regulatory activity commence, what is the definition of that? How do you reach the person? All that kind of information should be publicly available, conspicuously publicly available on the agency website. Second, since we now have a political appointee and it has raised significant questions, as you heard from Professor Strauss, what really needs to be done is to disclose all decisions by the RPO and the justification for that decision. It is not just about what is permitted to go forward but also what is stopped, and for that matter, what is permitted to go forward but altered in its approach. Third, we should have an annual report to Congress summarizing those activities. It should also be in the Unified Agenda, which is published in the *Federal Register,* so the public can see what is happening, but the documents that are exchanged internally in the agency should be sent to Congress in this annual report. And fourth in my points on the agency, and I won't go to five, all substantive communications, written or oral, outside the government or outside the agency including from OIRA should be docketed in the agency rule-making record. Moreover, for those activities that don't go forward, a new docket should be created about communications related to those that don't go forward.

Let me turn to OIRA and other kinds of reviewing entities. First, if a reviewing entity such as OIRA is now going to play a substantive role in rule-making review, it should be treated under our Administrative Procedure Act as involved in the rule-making and all of the various kinds of requirements that go with that should be held to OIRA. If it is really just going to be not the decider or the overseer, as Professor Strauss tried to distinguish, then maybe it doesn't apply, but it is clear that they are getting much more engaged in the substance. Secondly, all substantive communications, written or oral, particularly from outside of government, before during and after the OIRA review, should be docketed not only at

OIRA but again back at the agency level. Thirdly, OIRA should establish a government-wide standard for tracking rule-making so that the public can follow it from the beginning all the way through. You can't today. It is extremely difficult. And then fourth, the OIRA web site, which is incredibly important that administrators starting with Administrator Katzen, moving to Administrator Graham, have helped with transparency but the web site itself needs enormous improvement. It should be searchable. Right now it is just a long list of things to look at. Finally, the log that is used at OIRA for meetings with external players is at best inconsistent in what you get. Sometimes there is no title even of what the subject is. Almost never do you get anything about what the content of the meeting was about. You may get a list of participants. In any case, it needs to be complete, it needs to be consistent and it should be linked with that web site on what regulatory activities are happening so you know what is going on. I recognize that this adds burdens to agencies, but in an environment like this executive order, transparency is fundamental and essential to true accountability.

I want to just thank you, Mr. Chairman. This is now your second hearing. This is wonderful to find oversight, and I hope the oversight leads to action in terms of legislation. Thank you.

[The prepared statement of Dr. Bass follows:]

PREPARED STATEMENT OF GARY D. BASS

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify before you today. I am Gary Bass, Executive Director of OMB Watch. OMB Watch is a nonprofit, nonpartisan research and advocacy center promoting an open, accountable government responsive to the public's needs. Founded in 1983 to remove the veil of secrecy from the White House Office of Management and Budget (OMB), OMB Watch has since then expanded its focus beyond monitoring OMB itself. We currently address four issue areas: right to know and access to government information; advocacy rights of nonprofits; effective budget and tax policies; and the use of regulatory policy to protect the public. OMB Watch does not receive any government funding.

My testimony today focuses on 1) the responsibilities given Regulatory Policy Officers (RPOs) under Executive Order 13422, 2) the likely impacts of this regulatory change, 3) the current rule-making structure and disclosure requirements, and 4) OMB Watch's recommendations for improving transparency in the rule-making process in light of E.O. 13422.

Before addressing these points, I want to make clear to the Subcommittee that we strongly oppose E.O. 13422 and urge Congress to find a way to overturn the E.O. If that is not possible, we urge Congress to use its power of the purse to limit appropriations to implement some or all of the changes required by the E.O. The E.O. threatens public protections by further centralizing executive control over the regulatory process, removing agency discretion over legislative implementation, codifies regulatory delay, and substitutes free market criteria for public values of health, safety, and environmental protections.

I. President Clinton's Regulatory Policy Officer and Executive Order 13422

Executive Order 12866, Regulatory Planning and Review, created the Regulatory Policy Officer within each federal agency who reports generally to the agency head. The E.O. states:

> "The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive Order."

The role of the RPO envisioned in the 1993 E.O. is to coordinate and carry out agency responsibilities in regard to regulatory planning and review of regulations by the Office of Information and Regulatory Affairs (OIRA). These responsibilities include: allowing "meaningful" public participation in the regulatory process; in-

forming stakeholders of pertinent regulations; providing OIRA with a list of planned regulatory actions; providing OIRA with cost-benefit analyses for significant regulatory actions; and making available to the public information on proposed and final regulations.

In practice, the role of the RPO evolved differently. Not every agency maintains one designated RPO. In the case of the Department of Agriculture (USDA), various officials serve as de facto RPOs. Familiarity with the issue is likely to determine where responsibilities lie on a specific regulation. In the Department of Energy, the RPO also functions as an agency counselor. The RPO is not necessarily a political appointee, but the final regulatory decisions within an agency are in the hands of a political appointee, usually the agency head or his or her designee.

Two of President Bush's amendments to E.O. 12866 impact the RPO. First, agencies are now required to designate a political appointee as their RPO, and are to do so within 60 days of the issuance of the amendments, which should have already occurred. New text also requires OMB to verify this designation.

Second, in addition to changing the requirements of the designated RPO, the Officer's responsibilities are increased. The RPO will now be charged with approving an agency's Regulatory Plan, a responsibility previously given to the agency head. The amendments state that "no rule-making shall commence nor be included" for consideration in the agency's regulatory plan without the political appointee's approval. The Regulatory Plan includes the most important regulations which an agency plans in a given year.

II. The Impact of Executive Order 13422 on RPOs

E.O. 13422, the order that amended E.O. 12866 and was issued January 18, 2007, will solidify the position of RPO as the preeminent regulatory manager within each agency. By requiring the Officer to be a political appointee, the amendments suggest a further politicization of the regulatory process. OMB Watch is concerned that by installing a political appointee as the RPO and increasing the responsibilities, that appointee will significantly affect an agency's ability to regulate in a fair and nonpartisan fashion.

In some agencies, the amendments related to the RPO may have little effect on regulatory development. In the case of the Department of Energy, the RPO is already a political appointee albeit without the sole responsibility to initiate regulations and without final decision-making authority over regulations (unless one or both powers have been delegated to the RPO by the agency head). The White House is unlikely to have a greater or lesser impact on the way in which regulations are formulated within that agency. Similarly, the process in the Department of Labor is likely to go unchanged.

In other agencies, however, the RPO change will likely centralize the regulatory process and create OIRA-like structures within agencies even though OIRA has been criticized over the years for exerting political influence. In the case of USDA, this change, if followed, will end the process of dividing regulatory authority based upon experience and expertise. Instead, the RPO will ultimately be responsible for all regulatory decision-making and be involved in regulatory discussions from the beginning of agency considerations. Furthermore, installing a political appointee where one did not previously exist will facilitate White House input into agency regulatory matters.

A similar approach was attempted by President Reagan through his E.O. 12498, the Regulatory Planning Process, issued January 4, 1985. Under that order, agencies were to get approval from OMB prior to starting a rule-making—a pre-rule-making review. Many in the business community thought this would be an effective approach for choking off agency ideas in their earliest stage. That approach, however, proved too cumbersome and difficult to administer. E.O. 13422 revises this choke-hold by placing that de facto prior approval in the agencies themselves, instead of at OMB.

To ensure that the process works, the E.O. grants authority to these new political appointees to be the eyes and ears for OMB. And it mounts a challenge to congressional authority. When writing legislation, Congress often directs agencies to initiate a rule-making. The presence in the agencies of these appointees by whom rule-making must now be initiated will create a process that works as if Congress had not directed the agencies to act, or as if that direction is irrelevant if the White House appointees disagree with it.

Moreover, a requirement that has political appointees overseeing all regulatory matters raises a public perception concern. When a political appointee instructs scientists and agency experts to change what they are doing, it will raise questions about whether politics is superseding science. If RPOs are to be operating in this

way within agencies and are to be the points of communication with OIRA, then the need for transparency in the regulatory process has never been greater.

III. Current Rule-making and Disclosure

OMB Watch for years has urged Congress and the Executive to require more transparency in the regulatory process. This process 1) has become more centralized in the last three decades and, 2) despite improvements created by OIRA administrators Sally Katzen and John Graham still is not transparent enough. Especially during the current Bush Administration, greater access has been provided to those special interests who have the time, resources, and political influence to affect the outcome of the rule-making process. And the influence on agencies of both these special interests and of OIRA is now more difficult to determine because so much is done outside of the public's view.

We are concerned about transparency in two major directions. First, within the agency as the RPO takes on the new responsibility of initiating regulations, to what extent will the RPO allow politics to supersede the need for health, safety, environmental and civil rights protections as determined by agency experts?

Second, to what extent will the RPO be a de facto OIRA official sitting in the agency coordinating and carrying out the responsibilities of the OIRA desk officers during the pre-rule-making stage? Having been given the power to initiate regulations, we fear the RPO will further decrease agency rule-making discretion and increase the trend toward OIRA dictating agency rule-making. Transparency can prove our fear is groundless.

These transparency issues are concerns during both of the major time periods of the rule-making process: the pre-rule-making and rule-making (OIRA review/notice-and-comment) periods.

A. Pre-Rule-making Review

E.O. 12866 allowed OIRA to play an active role during the pre-rule-making stage when agencies are formulating annual plans for regulatory activities. Even more than the official rules, OIRA unofficially encourages agencies to discuss regulatory ideas at the earliest stages. By having OIRA involved in agencies' planning processes, OIRA can quash or alter any contemplated regulation before it is proposed for the Regulatory Plan. The communications between OIRA and the agencies are not disclosed, thus it is difficult to measure the extent to which OIRA exerts influence over the drafting of the proposed regulation that is finally submitted to OIRA. A Government Accountability Office report concludes that OIRA, by its own admission and by its involvement in the pre-rule-making stage, has significant influence over the proposed regulations agencies submit for review.[1]

Knowing that OIRA exerts this influence, it is critically important to document fully the pre-rule-making communications between OIRA and the agencies, or at least, the outcome of these communications. Despite OIRA's involvement in shaping the content and direction of agency rule-making, it is not covered by the basic statutory framework for the rule-making process—the *Administrative Procedure Act* (APA). Because OIRA is not covered by the APA, its activities are not public and not accountable.

This has become all the more necessary because of the changed role of OIRA during the Bush Administration. As former OIRA Administrator Sally Katzen testified earlier this year before this subcommittee, the intent of E.O. 12866 was to have OIRA be a "counselor" to the agencies:

> Executive Order 12866 retained centralized review of rule-makings, but also reaffirmed the primacy of the agencies to which Congress had delegated the authority to regulate. (Preamble) Among other things, Executive Order 12866 limited OIRA review to "significant regulations"—those with a likely substantial effect on the economy, on the environment, on public health or safety, etc. or those raising novel policy issues (Section 6(b)(1))—leaving to the agencies the responsibility for carrying out the principles of the Executive Order on the vast majority (roughly 85 percent) of their regulations.[2]

Instead of being a "counselor," OIRA has become a "gatekeeper" over agencies' proposed regulations. Before agencies submit proposed regulations to OIRA, the reg-

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[1] General Accounting Office, *OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews.* September 2003. Available at *www.gao.gov/cgi-bin/getrpt?* GAO–03–929. GAO changed its name to Government Accountability Office in 2004.

[2] Testimony of Sally Katzen, Adjunct Professor and Public Interest/Public Service Fellow, University of Michigan Law School before the House Committee on Science and Technology, Subcommittee on Investigation & Oversight, February 13, 2007, on "Amending Executive Order 12866: Good Governance or Regulatory Usurpation?" p.4.

ulatory outcome has already been determined. This power is exerted in several ways:

- In 2002, OMB issued its Data Quality Act Guidelines[3] which created new categories of information hierarchy. "Influential information" would now require a higher level of scrutiny than "information." OMB required agencies to issue guidelines, subject to OMB approval, establishing mechanisms to allow entities to challenge the accuracy of agency information and to report to OMB on the number and nature of these challenges.
- In 2003, OMB issued its Proposed Draft Peer Review Standards for Regulatory Science[4] which were widely criticized as too restrictive and too favorable to regulated industries. Furthermore, the draft standards provided another layer of OMB review of scientific and technical studies used in the pre-rule-making process. The Final Bulletin, issued December 2003, was an improvement over the draft but still left OMB in the position of overseeing peer reviews, selecting industry representatives for the panels, and requiring public comment on peer review conclusions which delays the rule-making process even further.
- In 2004, OMB issued Circular A–4[5] which describes in detail how agencies must conduct their Regulatory Impact Analysis (RIA), the basic cost-benefit analysis that must be provided for all economically significant proposed regulations. The RIA is the primary mechanism for justifying regulations and is the first point of review by OIRA desk officers.
- In 2006, OMB issued its Proposed Risk Assessment Bulletin[6] which, as do all of the above guidelines, tried to impose a one-size-fits-all standard on the way agencies were to conduct risk analyses. It, too, was widely criticized and finally withdrawn by OMB in January 2007 after a peer review by the National Research Council's concluded the document was "fundamentally flawed."[7]

As OMB Watch described in testimony before this subcommittee in February, these tools have been compromised by the issuance of these guidelines to further bias the regulatory process and threaten public health, safety, and the environment.[8]

1. Guidance review

In January 2007, OMB issued The Final Bulletin for Agency Good Guidance Practices[9], on the same day as President Bush issued E.O. 13422. The Bulletin requires internal review of significant guidance documents by senior agency officials as well as public notice-and-comment on guidance documents deemed "significant" or "economically significant."

The Bulletin first appeared in its proposed form late in 2005. It was announced in the *Federal Register* on Nov. 30, 2005, and was open for public comment. In those comments, public interest groups (including OMB Watch) criticized the Bulletin for its potential to allow OMB to interfere unnecessarily in agency practices. Industry organizations expressed their support for the Bulletin, citing their desire for OIRA to review guidance documents in the same way it reviews regulations.

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[3] Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies.* February 22, 2002. Available at *http://www.defendingscience.org/public_health_regulations/upload/Office-of-Management-and-Budget-Information-Quality-Act-Guidelines-2002.pdf.*

[4] Office of Management and Budget. *Final Information Quality Bulletin for Peer Review.* December 16, 2004. Available at *http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf.*

[5] Office of Management and Budget, *Circular A–4, Regulatory Analysis.* September 17, 2003. Available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf.*

[6] Office of Management and Budget, *Proposed Risk Assessment Bulletin.* January 9, 2006. Available at *http://www.ombwatch.org/regs/2006/riskassessmentbulletin-draft.pdf.*

[7] National Research Council, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget.* January 11, 2007. Available at *http://www.nap.edu/catalog.php?record_id=11811.*

[8] Testimony of Rick Melberth, Director of Regulatory Policy OMB Watch before the House Committee on Science and Technology, Subcommittee on Investigation & Oversight, February 13, 2007, on "Amending Executive Order 12866: Good Governance or Regulatory Usurpation?" Available at *http://www.ombwatch.org/regs/PDFs/Melberth_testimony.pdf.*

[9] Office of Management and Budget, *The Final Bulletin for Agency Good Guidance Practices.* January 18, 2007. Available at *http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf.*

As OMB Watch reported in our final analysis of the new E.O. and the Good Guidance Practices Bulletin[10], the Bulletin defines guidance documents to include "interpretive memoranda, policy statements, guidances (sic), manuals, circulars, memoranda, bulletins, advisories, and the like." Federal agencies issue thousands of guidance documents each year relating to hundreds of different types of activities.[11]

As Section 9 of the amended E.O. also clearly states, the OIRA administrator has the power to determine which guidance documents are significant, thus submitting them to the review process, as well as when "additional consultation" is needed before a document can be issued. Section I(4) of the Good Guidance Practices Bulletin provides that the head of an agency, "in consultation and concurrence" with the OIRA administrator, may exempt categories of significant documents from the Bulletin's requirements.

Section I(5) of the Bulletin adds a further category of guidance document, the economically significant guidance document which is:

> "a significant guidance document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include guidance documents on federal expenditures and receipts."

The definitions of both significant and economically significant guidance documents include documents that "may reasonably be anticipated to lead to" certain conditions. This language applies to all four conditions in the definition of significant guidance document,[12] and the Bulletin "makes clear that the impacts of guidance often will be more indirect and attenuated than binding legislative rules."

While the proliferation of agency guidance documents may well deserve attention, the solution is not additional OIRA review. If anything, the growth of agency guidance indicates that the existing regulatory process is broken.

2. Guidance and the RPO

This is an area in which the RPO may effect significant change even in those agencies, like Labor and Energy, where the RPO has already been a political appointee. Under E.O. 13422, OMB can now engage the agency, along with other government personnel (as provided for in one amendment), in reaching a "common understanding" on regulatory efforts through the presence of the RPO.

After internal agency approval by the RPO, the agency will send drafts of significant guidance documents to OIRA for review. The RPO is responsible for ensuring that the agency sends a draft of the significant guidance to OIRA, along with an explanation of the need for the guidance and how the guidance document will meet that need. The fourth part of the guidance definition, raising "novel legal or policy issues arising out of legal mandates, the President's priorities, or principles set forth in this Executive order," is nearly broad enough to permit OIRA to sweep into its review any guidance it wishes to review. It is likely that the RPOs, in reaching that "common understanding", will be the ones providing that internal approval.

Beyond this grant of authority to review significant guidance, there is little explanation in the Bulletin of OIRA's role in the review process. Unlike the detailed procedures for OIRA's review of regulations, the procedures for OIRA's review of guidance is relatively vague. OIRA will "notify the agency when additional consultation is required before the issuance of a significant guidance document." There are no timelines for completing the review, and there is vague language about the administrator's ability to exempt guidance for an emergency or "other appropriate consideration."

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[10] OMB Watch, *A Failure to Govern: Bush's Attack on the Regulatory Process.* March 2007, p. 16. Available at *http://www.ombwatch.org/article/articleview/3774.*

[11] Congressional Research Service, *Changes to the OMB Regulatory Review Process by Executive Order 13422,* February 5, 2007. p. 10. Available at *http://www.ombwatch.org/regs/PDFs/CRS-EO13422.pdf.*

[12] Section 3(h) of E.O. 13422 defines a significant guidance document as "a guidance document disseminated to regulated entities or the general public that, for purposes of this order, may reasonably be anticipated to: (A) Lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (B) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (C) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or (D) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order."

B. Rule-making Review and Public Comment

Currently, the public can first learn about an agency's intentions to regulate through the semi-annual Unified Agenda which is published in the *Federal Register.* It is notoriously inaccurate in its reporting of agency regulatory work and timing of an agency's activities. Nonetheless, it is an important document that should be improved.

In reality, the public first learns of a specific agency regulatory activity from a website operated by OIRA when OIRA logs agency regulatory submissions for review. The website is meager, however. The public cannot search for a rule; instead, there is a long list of rules sorted by departments.

E.O. 13422 does not amend the rule-making review procedure significantly; its impact is in the pre-rule-making stage. In conjunction with the Good Guidance Practices Bulletin, however, it establishes OIRA review and notice-and-comment procedures over agency guidance documents.

By subsuming guidance documents to a review process almost identical to the review process OIRA uses to review and approve regulations, the extent of OIRA's reach into agencies' responsibilities will be at an all-time high, as will the influence and access of regulated sectors. As a result, the administration has unilaterally redefined the Administrative Procedure Act, which specifically exempts interpretive rules and policy statements from the notice-and comment process. All of the documents deemed significant will now come under review by OIRA's staff of about 55 people and go through the regulatory notice-and-comment period—but only after being vetted by the RPO.

1. OIRA Review

OIRA has 90 calendar days to review a proposed regulation after submission, but this can be extended. Desk officers review the RIA developed according to OMB's Circular A–4. Review is required only of significant regulations, but OIRA has the authority to review those deemed non-significant as well. Although there often is extensive communication between OIRA and the agency during pre-rule-making, OIRA has used "return letters" and "prompt letters" to indicate to an agency areas in which the proposed regulation has deficiencies, or to urge an agency to take regulatory—or deregulatory—action.

According to section 8 of the E.O., during the review period, an agency is not permitted to publish the proposed rule in the *Federal Register* until the OIRA administrator notifies the agency that OIRA has completed or waived its review or the applicable time limits for review have expired. Even without a response from OIRA, the agency must seek presidential consideration through the Vice President before publishing the regulatory action.

Section 6 of E.O. 12866, *Centralized Review of Regulations,* describes the disclosure requirements OIRA must follow during and after the review period:

> (4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:
>
> (A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;
>
> (B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines:
>
> (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);
>
> (ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and
>
> (iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the *Federal Register* or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

While OIRA publishes some of this information on its website or Reginfo.gov, much of the information is not available to the public, but is only available, if requested, in its docket room. In October 2001, OIRA Administrator John Graham issued a memorandum clarifying OIRA procedures for disclosure and acknowledges OIRA's intent to add more information in compliance with the E-government plans of the administration.[13]

There are many areas, however, that are not covered by the disclosure policies. For example:

- **Rules not under review are not covered** by its disclosure policy: "Rules are not under review prior to the start of informal OIRA review or after OIRA has notified the agency that review is concluded; legislative discussions are not covered." Thus, informal OIRA pre-rule-making activities are not public.
- **Meetings with parties outside of government about rules not under review are not covered.** Regarding meetings with outside parties, "any meeting" to discuss the substance of an individual rule is covered, but "Meetings to discuss rules not under review, or meetings to discuss broad regulatory topics (e.g., analytic methodology or legislation)" are not covered. Moreover, even for those meetings that are disclosed, the disclosed information is inconsistent. The disclosure sometimes omits participants' affiliations, or rules or topics discussed.
- **Correspondence about rules not under review are not covered.** "Correspondence received while a rule is not under review" is not covered by the disclosure policy.
- **Internal communications are not disclosed.** "Outside parties," for purposes of disclosure, are "persons not employed by the executive branch." So communications with Congress and the public are disclosed, but not inter- and intra-departmental communications.
- **Substantive communications are not defined.** "Substantive communications" are not defined while "non-substantive discussions" are defined only by providing examples like "status of review, review procedures." What kind of communications are classified as substantive, and how does the public know these policies are being followed?

These kinds of loopholes abound throughout the memo. Limiting disclosure to information and communications generated during the 90 or so days the rule is under OIRA review ignores the years involved in developing rules under the current process. There is extensive communication within and among agencies, agencies and OIRA, agencies and the regulated communities, OIRA and the regulated communities, etc. None of these communications are shared publicly as part of OIRA's disclosure policies. The opportunities for influence to be exerted in multiple directions are extensive.

In addition, these disclosure requirements are far too limited in light of publication of agencies' regulatory plans in the Unified Agenda. Proposed regulations don't

[13] John D. Graham, OIRA Administrator, *Memorandum for OIRA Staff: OIRA Disclosure.* October 18, 2001. Available at *http://www.whitehouse.gov/omb/inforeg/oira_disclosure_memob.html.*

just appear one day as submissions to OIRA. Limiting disclosure to the 90 day period of OIRA's review is like shining a flashlight on an item when electricity is available.

2. Notice-and-Comment Period

The publication of a proposed rule in the *Federal Register* triggers the public participation phase of the rule-making process. The notice-and-comment requirements under Section 553 of the APA outline this public process and have been subject of criticism and litigation for years.

> The traditional view of section 553 procedure as a process for educating the agency has, however, been gradually replaced, in practice if not in theory, by the belief that informal rule-making procedure should provide interested persons an opportunity to 'challenge the factual assumptions on which [the agency] is proceeding and to show in what respect such assumptions are erroneous.' In other words, the public must be informed of the data and assumptions on which the agency's proposal is based.[14]

Anyone who has tried to comment on or review the comments of others during this period knows that the information available to the public is far from the standard Professor Lubbers describes above. Information from agencies is incomplete or not available, opportunities to comment on some rules open for comment don't exist on electronic dockets, and the opportunity to see who has commented and what those comments address is too often non-existent.

Furthermore, as this subcommittee well knows, the Bush Administration has distorted science, chilled scientific speech, and manipulated regulatory tools in pursuit of ideological ends. OMB Watch encourages the Subcommittee and Congress to examine the entire regulatory process for opportunities to increase transparency in the public process and in the substance of the information available. To that end, OMB Watch has recommendations for specific ways in which regulatory transparency could be improved.

I want to again express our opposition to E.O. 13422 and urge Congress to overturn the E.O. Short of that option, we urge Congress to use its appropriations powers to limit the executive's ability to implement some or all of the E.O.

IV. Recommendations for Improved Transparency

One serious concern with the advent of a politically appointed RPO in each agency is that the interests of the RPO may become more closely aligned with those of OIRA and the White House than with those of the agency in which the RPO works, with public sentiment and need, or with scientific consensus on an issue. If the RPO now has the ability to initiate regulations, then the point at which agency personnel reach a decision to recommend regulatory action, and make that recommendation to the RPO needs to be clearly defined. We recommend the following:

A. Agency Responsibilities

1) That each agency clearly identify the RPO, provide a description of that person's role in regulatory matters, and how the public can contact that person. The information should be conspicuously available on agency websites.
2) That each agency be required to disclose with its regulatory plan, those proposed regulatory activities that the RPO has decided the agency will not pursue. The plan and the ideas and proposed regulatory activities discarded or delayed should be published in the Unified Agenda published semi-annually in the *Federal Register* along with justification for the delays or decisions not to undertake the activities.
3) That the public should have the right to obtain from the RPO clarification of items in the plan in addition to the items rejected or delayed.
4) That each agency provide formal documentation of ideas generated by agency personnel regarding activities that may lead to regulatory actions. This documentation requires:
    a) A clear definition of when a regulatory action commences. For example, a regulatory action commences at the point at which an agency employee or contractor transmits a recommending document to the RPO or starts a formal communication on the matter.

[14] Jeffrey S. Lubbers, *A Guide to Federal Agency Rule-making.* (Chicago: ABA Publishing, 2006.) p. 298–9.

b) Within a very short period, for example, 30 days, the RPO publishes a written response to recommending actions with justification for declining, agreeing, or other actions regarding the recommendation. The public must be assured that the RPO's decision to stop a rule from being developed is not a triumph of politics over responsible government.

c) Placing all documents in the agency rule-making record for activities that move to the proposed rule-making stage and creating a new public docket, available through the Internet, of all other actions (i.e., those not pursued).

5) That agencies submit an annual report to Congress on activities that have been delayed, withdrawn, or rejected by the RPO and the justifications for such actions.

6) That all intra-agency communications, written and oral, between the RPO and the agency personnel responsible for developing the proposed regulation be documented and included in the agency's rule-making record.

7) That all inter-agency communications, written and oral, be documented and included in the agency's rule-making record.

B. Reviewing Entities Responsibilities

This section covers the role of OIRA and other reviewing entities such as the Small Business Administration (SBA).

1) That "substantive" communications be defined and not left to individual discretion.

2) That all substantive communications, written and oral, between the agency and the reviewing entities be documented and included in the agency's rule-making record.

3) That all substantive communications between parties outside of government, and excluding communications with the President, and any party involved in the rule-making process (agency or reviewing entity) be documented and included in the agency's rule-making record. This disclosure covers materials submitted by the outside parties, and documentation of oral and written communications.

4) That OMB establish a government-wide regulatory tracking system. As part of the implementation of the E-Government Act of 2002, agencies should develop a regulatory tracking system by which the public can follow a regulation through each step of the rule-making. Currently, there is an e-rule-making approach being refined on Regulations.gov. Each agency should provide a clear process by which regulations can be tracked through this system with appropriate links to the information contained in the rule-making record.

5) That OIRA's website be searchable, with information consistent for each record, and with identification numbers that link records clearly to the regulatory actions with which they are associated.

6) That meeting logs, made available through OIRA's website, be complete and include the purpose of the meeting, generally what was discussed, the participants and their affiliations, a brief description of materials circulated, and any conclusions or outcomes that resulted from the meeting.

If OIRA and other reviewing entities like the SBA continue to have significant impact on the substance of agency rule-making, then the APA informal rule-making process should apply to these reviewing entities. It is unfair to the agencies who are sued as a result of rule-making actions to bear the full burden of litigation when they do not have full responsibility for the substantive rule-making outcome. If the APA needs to be amended to cover these reviewing entities, then we urge Congress to take appropriate action.

We realize the burden of this transparency proposal falls primarily on the agencies. But until and unless the reviewing entities which influence the substantive outcome of regulatory activities are subjected to the same APA rules, the agencies must be the repository for the full rule-making record.

Subjecting agency guidance documents to the same APA-like review process requires the same level of transparency, record development, and information access we are recommending for rule-making. After all, OMB's justification for subsuming agency guidance into the review process is that agencies are using guidance to avoid the rule-making process. Therefore, the transparency principles should apply to review of guidance documents as well.

Post notice-and-comment communications may be helpful to agency and the reviewing entities. The decision to limit or accept these communications should be left to the agencies. But the same principles apply if agencies decide to allow communications at this point: the communications and identification of the parties should become part of the record. Similarly, OIRA's and other entities communications with parties after the notice-and-comment period should become part of the agency's rulemaking record. These principles of open and transparent decision-making should apply to a second notice-and-comment period if deemed necessary.

In addition to helping to restore trust in government by providing transparency, the ability to evaluate regulatory outcomes is greatly enhanced by having the substantive basis of decisions available to the public. Congress, the President, other government agencies responsible for providing information to these branches, state decision-makers and policy staffs, researchers, and other segments of the public can access, analyze, and share information. The technological advances that have occurred make this transparency far easier than was possible in past decades. As the Federal Government moves to increased transparency in its interaction with the public, our political dialogue is enhanced by providing more information, and using that information to achieve increased government effectiveness and efficiency.

Thank you for the opportunity to testify.

BIOGRAPHY FOR GARY D. BASS

Gary D. Bass is the Founder and Executive Director of OMB Watch. Since founding the advocacy organization in 1983, Dr. Bass has testified before Congress, appeared on national television, addressed groups across the country, and written extensively on federal budgetary, program management, regulatory and information policy issues.

Dr. Bass is well known for assisting nonprofit organizations in better understanding federal rules affecting their organizations and constituencies and was recently selected as one of the *Nonprofit Times* Power and Influence Top 50. He has led campaigns to preserve the advocacy voice of nonprofits, make Federal Government a more open and accountable operation, and insure meaningful citizen participation in government decision-making. He has been an active supporter of right-to-know initiatives, encouraging the government to make information publicly accessible in order to empower its citizens. He has also undertaken initiatives to insure that, as we move into the information age, we do not create a society of information haves and have-nots.

In 1989, he created RTK NET (the Right-to-Know Network), a free online computer service to provide community groups with access to government data. More than 3,000 people now use RTK NET to get access to government data about toxic chemicals, census, housing demographics, home mortgage activity, and campaign finances. He has been a pioneer in identifying ways in which the information superhighway can be a tool for those working in the public interest sector.

During 1995, Dr. Bass led OMB Watch in challenging a number of provisions in the Contract with America, and successfully formed a number of coalitions that stopped proposals that would have undermined our society's safety net. Working with organizations representing working men and women, as well as those representing environmental, educational, civil rights, human needs, religious, consumer and other public interest concerns, he stopped: a "no money, no mandates" measure that would have resulted in state and local governments being exempted from complying with federal laws, such as fair labor standards, civil rights protections, and voter registration laws; a constitutional amendment to balance the U.S. budget that would have seriously harmed human service delivery in this country; a variety of regulatory provisions that would have undermined health, safety, and environmental protections and safeguards; and an effort to silence the advocacy voice of charities across the country.

Over the years, Dr. Bass has stressed the importance of educating community groups about federal issues. He has led many nationwide briefings on issues ranging from changes in human services programs during the Reagan Administration to balanced budget initiatives, to issues pertaining to the advocacy voice of the nonprofit sector. He has also employed the use of e-mail to establish two-way communication with community groups on these issues.

Prior to founding OMB Watch, Dr. Bass was President of the Human Services Information Center, where he wrote two books and numerous articles on human services issues, and published the Human Services *INSIDER*, a bimonthly newsletter on the politics of federal human services program. He had also served as: Director of Liaison for the International Year of Disabled Persons; consultant on several projects in special education and the mental health of children, youth, most notably,

the preparation of the first annual report to Congress on the implementation of the *Education of All Handicapped Children Act* (P.L. 94–142); Special Assistant to Wilbur Cohen, then Chair of the Michigan Governor's Task Force on the Investigation and Prevention of Abuse in Residential Institutions; and in juvenile justice and community corrections.

Dr. Bass received a combined doctorate in psychology and education from the University of Michigan, along with the University's highest award for graduate student teaching and several awards for academic excellence.

Chairman MILLER. Thank you, Dr. Bass. Dr. Bass, I know that your red light was on. You said you had five points; you made four and didn't make five. Do you wish to make the fifth? All right.

Dr. Richard Parker.

STATEMENT OF MR. RICHARD W. PARKER, PROFESSOR, UNIVERSITY OF CONNECTICUT LAW SCHOOL

Mr. PARKER. Thank you. Mr. Chairman, I appreciate this opportunity to review some observations on Executive Order 13422.

Over the past 20 years, I have had a chance to observe the regulatory process from a number of different vantage points from the private sector, from within agencies, both in the Reagan Administration and the Clinton Administration and from academia. The only perspective I haven't had is your perspective, the perspective of the Oversight Committee, but that is obviously a very, very important perspective. And I will have to say that, you know, when I view this issue vicariously from your perspective, it seems to me that the entire institution of OIRA review of agency policies is distinctly problematic and E.O. 13422 should be viewed as a small but significant step in that already problematic direction.

What do I mean by that? Well, by extending OIRA oversight to guidance documents, we focused on transparency. Not only does E.O. 13422, but all the executive orders, have hugely expanded the power of an agency that has basically no scientific or technical expertise to shape policies that often have a very important scientific and technical component. It extends the power of an agency that has a troubled history in acting as a conduit and through back channels for special interests, to guidance documents now beyond regulatory documents, and I just wanted to echo what Dr. Bass just said about this problem of informal reviews. When I was talking to old friends from various agencies about what I should say in this hearing, just an open-ended question, what worries you most, the first thing that came out was these informal reviews which basically are backroom things that they are instructed not to report to anybody but which turn out to be very influential in shaping the rules from the get-go. So I just want to second Dr. Bass's comment on that based upon what I have been hearing from the trenches.

The RPO issue I think has been dealt with extensively. I won't elaborate on that except to say I support it.

The issue is that basically where are we going and why are we here. White House intervention in rule-making is not required by the Constitution in the area that we are talking about. It is not mandated by any statute. And the question arises, given the costs to transparency, to expertise that we have been talking about, what is it that justifies this kind of intervention at all. I would like to just sort of think about this from a cost-benefit standpoint. We have seen the costs. What are the benefits? And I will have to say

that procedural steps are very hard to quantify. Their benefits are very hard to quantify, and if my colleague were still with me, I would point out that there are regulatory critics who basically zero out benefits of procedures that can't be quantified and so by that standard, the entire institution of OIRA review would have to be assigned a zero benefit in a cost-benefit analysis. I can't play that game because I favor the inclusion of qualitative benefits and so I have to do a little more work, but we need to talk about what is it that OIRA is bringing to the process, and it seems to me that if you go back through history, the reason that OIRA was brought in, and the thing that has been driving this entire dynamic from the get-go has been a profound skepticism of the competence of agencies and certainly of their evenhandedness. Going back to the 1980s, there was this view that EPA is full of environmental whackos who think the polar icecaps are melting or something. At OSHA, you know, just full of these zealots who can't stop pushing out regulations; we have to rein them in. And if you recall from the 1980s and the 1990s, in particular when these institutions were getting entrenched, there was an endless litany of horror stories of regulatory abuses, and I will tell you, I was bothered by this litany and I started investigating some of these stories and I published the results of my investigations in two major articles, and I can only summarize, but I can tell you in a nutshell that what I found is that these stories basically can't be verified in most cases. Many are gross exaggerations. Some were just complete fabrications, and I could give you an example. There are some stories of course that are true. I mean, in any case there are genuine problems. But there has been no documentation of a pervasive problem of agency overzealousness that would warrant this institution in the first place.

The other great sort of foundation stone of this regulatory skepticism that gives us OIRA review has been a series of three really major studies that looked broadly at regulations and all done by regulatory critics, all very widely publicized over a period of decades and all coming to essentially the same conclusion, that while regulation is overall beneficial, there are many regulations that fail cost-benefit analysis. So what I did was, in these articles I looked at the three most influential studies and I looked at the data behind them and the methodology behind them, and what I was surprised to find frankly was that they just don't stand up. None of these studies have been peer-reviewed. Their samples are biased. They substitute educated guesses for the cost benefits of regulations and report them as ex post actual costs and benefits. But most of all, they zero out whole categories of regulatory benefit, and when I actually looked at one of the most influential studies that had been widely quoted to promote this regulatory skepticism, I found out that 41 of the 136 rules in the database were assigned a zero benefit, not a zero net benefit but a zero benefit because the benefits that those regulations provided had not been monetized and quantified by the agency. They were qualitative benefits like the benefits of freedom, like the benefits of enforcement. The list of zero-benefit rules included rules to prevent major oil spills like the Exxon Valdez, a rule to protect 3.9 million agricultural workers from acute pesticide poisoning. Here the rationale was that acute

pesticide poisoning wasn't one of the harms to which we had detailed monetary value, so they zeroed it out. All right. So the point is that these studies are not peer-reviewed studies and I just would like to suggest before we go further down the road of OIRA intervention perhaps OIRA intervention itself ought to be subject to a cost-benefit analysis. Perhaps we ought to look at the empirical basis underlying the entire project of White House intervention and expert rule-making.

Let me just close by saying that I don't want to be interpreted as saying that there is nothing wrong with agency rule-making, that there are no bad rules. There are. I suspect though that when you look, you will find agencies making errors both in underregulating and overregulating. But in any case, the way to correct bad rule-making is public involvement, it is expert involvement, it is transparency, it is openness, and unfortunately, this executive order is not about public involvement. This executive order is about building OIRA's turf and therein lies the problem.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Parker follows:]

PREPARED STATEMENT OF RICHARD W. PARKER

Mr. Chairman and Members of this subcommittee, I appreciate this opportunity to share with you some observations on the Bush Administration's amendments to Executive Order 12866, particularly Executive Order 13422. I have studied and taught administrative and environmental law—and regulatory policy—for over a decade; published articles in leading scholarly journals on the subject of OIRA review and the use of cost-benefit analysis; and benefited from sustained participation in work of the Administration Law Section of the ABA, where I have co-chaired both the Regulatory Policy Committee and the Committee on e-rule-making. I have served as Special Counsel to the Deputy Administrator of EPA during the Clinton Administration and as Assistant General Counsel of USTR. And I practiced administrative law in the private sector. So I have had a chance to observe these issues from a number of different vantage points. My remarks today represent, of course, my own view of the matter.

Is E.O. 13422 good governance or regulatory usurpation? The answer to that all depends on whether you buy the premises—the theory of government—that animates it and that animated its forebears, the Reagan/elder Bush Executive Orders and E.O. 12866 itself. These Executive Orders embody a view of our executive agencies that is deeply skeptical of their competence, and certainly of their even-handedness. Certain regulatory agencies—particularly those in the field of health, safety and environmental regulation—are thought to be tunnel-visioned; obsessively focused on regulation regardless of cost; and unaccountable to the people. They need to be reined in and OIRA is just the agency to come to the rescue. OIRA will impose a broad perspective which once had been narrow; require cost-benefit analysis to force a more rational and even-handed balancing of costs and benefits in regulation; and bring political accountability to a process that otherwise would operate without popular or political check.

If you buy this vision, then E.O. 12866 is the order for you, and if you further buy that guidance documents are first and foremost tools of choice for agencies intent on exploiting "loopholes" to avoid the rationalizing benefits of OIRA review in the rule-making process then E.O. 13422 is likewise for you.

But it is view right? Is it based on rigorous empirical observation and sound science? Or is it more like the widespread belief in Iraqi weapons of mass destruction circa 2003—immensely plausible, boasting bipartisan support, but somehow a bit lacking in the evidence department? I investigated these questions systematically in two major articles, one published in the *University of Chicago Law Review* and the second in the *Administrative Law Review.* They are long articles and I can only summarize them briefly here; but the main takeaways are clear.

Let's begin by clearing away some underbrush—an activity that now has strong bipartisan credentials. Regulatory critics such as the Mr. Kovacs who testified before this subcommittee in February not uncommonly point to the size of the *Federal Register* and the number and cost of rules as evidence of the "overwhelming regu-

latory burden" our industries face. 73,000 pages of *Federal Register*! 4000 new regulations each year! $1.13 trillion cost! Horrors!

In fact, any perusal of the any *Federal Register* quickly reveals that the *Federal Register* carries far more than new rules. New rules comprise only a small fraction of its contents. Moreover, even the new rules published in the *Federal Register* typically consist of roughly 20 pages of preambular explanation for every page of rule. These 20 preambular pages are actually explanations and defenses of the rule, along with detailed responses to comments from the public that can run to the tens of thousands. Far from adding to burden, agency explanations lighten the load by easing understanding of the basis and purpose of the rule being proposed or promulgated. But they do add length to the *Federal Register*.

As for the rules themselves, length should not be confused with burdensomeness. Congress could reduce the environmental statute books (now two inches thick) to one line: "Thou shall not pollute." Does anyone truly believe that this would make regulation less onerous? Much of the length and complexity of modern rule-making stems from the desire to make it reasonable, not from some tunnel-visioned attempt to make it harsh.

Admittedly, four thousand rules per year does seem like a lot, at first blush. But a sophisticated user of numbers will ask, is this really a large number—given our $12 trillion economy and population of 270 million, not to mention millions of businesses spanning hundreds or thousands of different kinds of activity? Remember also that it takes a regulation to ease a regulation. It takes a regulation to alter so much as a comma in a prior regulation. Many regulations are minor and technical. Others make changes in the direction of providing greater clarity or greater leniency. This being so, the mere number of "regulations" in itself tells you nothing meaningful about regulatory burden.

And what of the alleged $1.13 trillion cost? That figure, if accurate, is a large figure even when viewed in context of our more than $10 trillion economy. But that number comes not from OMB but from the Small Business Administration and I wonder whether it has been rigorously peer reviewed. The numbers I have seen commonly range from $200 billion to $700 billion, and even those numbers are derived not from actual measurements but from *ex ante* predictions of cost often supplied by industry. Moreover, most of these costs are accounted for by a relative handful of rules that also bring with them enormous benefits: like water safe to drink, air safe to breathe. No credible study yet done—even by OMB—has yet concluded that the net benefits of rules as whole are negative. In fact, all observers concede that benefits of regulations greatly outweigh their costs overall. So what are we to make of the allegedly exorbitant aggregate burden of regulation?

Michael Porter of Harvard Business School is one of many prominent scholars who have joined leading businesses like 3–M and Dupont in pointing out that regulations don't just add costs. Regulations can create lucrative markets, promote technologies, build industries and enhance American competitiveness in producing the goods and services of tomorrow. Many companies discover important new money-saving efficiencies in the course of auditing their production process to comply with regulations. Yet none of these countervailing economic benefits of regulation are factored into (or subtracted from) the gloom-and-doom cost estimates that are routinely bandied about by leading regulatory critics.

In short, the case for more searching OIRA review cannot be made credibly by throwing out *Federal Register* page counts, or by tossing out aggregate cost statistics that are exaggerated and then offered in isolation without the context of their benefits. There is a need for sound science in regulatory criticism as well as in regulation itself.

If *Federal Register* page counts, and aggregate cost quotes do not make the case for the necessity and value of ever-expanding OIRA oversight, what then does?

My in-depth research of this very question reveals that for decades, scathing critiques of government have been fueled by a stream of horror stories which are typically unverified and many (though not all) of which turn out, on inspection, to be either exaggerated, atypical or just plain false. My University of Chicago article offers a few anecdotes to illustrate the pitfalls of legislating by anecdote.

Secondly however, and much more importantly, regulatory skepticism and arguments for cost-benefit analysis and OIRA oversight of agency regulations (and now guidance documents) have been fueled by a group of studies called "regulatory scorecards," which examine a broad array of major regulations to conclude that while regulation overall may be beneficial in aggregate, the costs of many individual government regulations vastly outweigh their health, safety or environmental benefits.

For example, since at least 1986, a widely-cited table by John Morrall, an OIRA economist, has served as Exhibit A for the proposition that federal agency regulation—particularly regulation of workplace and environmental toxins—is pervasively

over-zealous and irrational. He reported that over a third of the 44 regulations in his database cost more than $100 million per life saved, and one infamous regulation, OSHA's formaldehyde rule, cost $72 *billion* per life.

How can this be? Well, to begin with, I and other scholars have shown that he did not draw on a random sample of regulations in setting up his database, but rather cherry-picked the toxin regulations that he deemed most problematic. Secondly, he freely acknowledges that he substituted his own preferred benefit numbers for agency benefit estimates whenever he found a supporting study (names of which he has yet to disclose) which he found more credible than the studies that agency scientists and science advisors had relied upon. For example, in 1985 OSHA estimated that its proposed formaldehyde exposure regulation would save from six to forty-seven lives over forty-five years. Morrall alters that estimate to one life saved every hundred years.

This is a rather significant change. One wonders what qualifies Mr. Morrall, an economist, to second-guess panels of agency scientists on the issue of the relative merits of different risk estimates. I dwell on this because the practice of altering or challenging agency science and scientific assessments is not confined to Mr. Morrall, or his table. It reflects long-standing OIRA practice that persists to this day. In fact, Administrator Graham has tacitly recognized the competence concern by hiring one or two toxicologists and other physical scientists to provide a scientific fig leaf for OIRA second-guessing of agency scientific judgments. But is that the way science is supposed to work? My understanding is that science works not by privileging the opinions of one or two particular scientists on the basis of their government position—or their appeal to a sympathetic economist—but by seeking a consensus in the scientific community on how to evaluate the evidence.

Finally, my research shows that Mr. Morrall achieved his shocking figures in part by simply excluding—zeroing out—benefits that did not conform to his procrustean template. Again, the infamous $72 billion per life formaldehyde rule will illustrate the point. What Morrall's table conceals, but which the rule-making record reveals, is that OSHA's rule (beyond preventing about one cancer fatality per year) which, in Morrall's hands, becomes one-hundredth of a fatality per year, after adjustment and discounting, was also expected to yield a host of unquantified but clearly substantial benefits of a non-life-saving nature.

Indeed, the rule-making record makes clear that OSHA's formaldehyde rule was never justified as a life-saving rule at all. The non-life-saving benefits and purposes of the rule are delineated at length in the preamble to OSHA's proposed rule: reduced or avoided burning eyes or noses, sore or burning throats, asthma attacks, chronic bronchitis, allergic reactions, dermatitis and skin sensitization. OSHA notes that over 500,000 American workers are regularly exposed to formaldehyde at concentrations that have been found to cause one or more of these illnesses or discomforts.

The central policy questions for OSHA were, "Is avoiding such discomforts and health hazards for 500,000 American workers worth the expenditure of $36 million a year by a $30 billion dollar group of industries? Will installing ventilators in the workplace also reduce employee exposure to other irritating and possibly hazardous chemical vapors?" These questions are quite unlike (and are far more complex than) the question implicitly posed by the Morrall table: how could OSHA be so stupid as to propose a rule that will cost $72 billion for every life saved?

I dwell on this point because, again, the Morrall table is not an isolated case. Unfortunately, it is all too typical of the approach that OIRA has taken, particularly in this Administration, to regulatory oversight and cost-benefit analysis. Widely accepted principles of cost-benefit analysis call for the inclusion of non-quantifiable or non-monetizable benefits. In principle, non-quantified benefits are recognized and respected. E.O. 12866 calls for qualitative benefits to be included and described in all regulatory impact assessments. Qualitative benefits are often described, at least perfunctorily, in OMB's Reports to Congress on the Costs and Benefits of Regulation.

It is the practice wherein the problems lie. In practice, agencies know that any benefits that cannot be quantified are likely to be zeroed out in the mill at OMB. They know that basing a decision on un-enumerated *judgment* that the costs of a policy or action are "worth" the benefits is perfectly fine for foreign policy, perfectly fine for defense procurement, perfectly fine for most areas of government and perfectly fine for most decisions in daily life—but it means rough sledding for health, safety or environmental regulations at OMB.

The problem is that you can't make regulatory policy by the numbers any more than you can draw or paint by the numbers. Many benefits are either hard or impossible to quantify and monetize in a scientifically defensible way. How do you put a monetary value, for example, on a procedure that aids enforcement, or deters

wrongdoing, or provides useful information to consumers? How do you put a value on the benefit on a policy that itself will not solve a problem, but that forms a part of a mosaic of responses and diplomatic initiatives needed to address that problem effectively? How do you put a value on preserving the environment, when our understanding of ecological risk and benefit is so extremely limited, and our methods for valuing environmental amenities so crude? In practice, OIRA insists on viewing regulatory policy through the prism of numbers. Yet many health, safety and environmental regulations cannot be evaluated sensibly on the basis of numbers alone.

Nowhere are the consequences of this flawed approach to policy more apparent than in the analysis proffered by Robert Hahn of the AEI–Brookings Joint Center for Regulatory Studies, a leading regulatory critic and a leading proponent of not only enacting E.O. 13422 but extending it further to require cost-benefit analysis of agency guidance documents as well as rules.

The prevailing approach to regulatory critics to regulatory assessment is evident in his much-heralded and influential studies—one in 1996 and another in 2000—which purport to show, based on a wide-arranging analysis of over 130 major rules spanning a ten-year period, that 57 percent of all major environmental regulations "fail a neutral economist's cost-benefit tests." This is a powerful indictment of health, safety and environmental regulation—until one learns that 41 of the 136 major regulations appearing in Hahn's tabulation are assigned a *zero benefit.* Not a zero net benefit, but a zero benefit, meaning the regulations have no use whatsoever. The list of zero-benefit rules includes:

— a rule to protect 3.9 million agricultural workers from exposure to harmful pesticides;
— a rule requiring that owner/operators of tankers develop plans to respond to large oil spills;
— a rule to require that air polluters hold comprehensive permits which lay out their pollution control obligations;
— a rule requiring the public reporting of releases of certain toxic chemicals from large manufacturing facilities;
— a Clean Water Act rule aimed at protecting sensitive coastal areas from non-point-source water pollution;
— three rules establishing national primary drinking water standards to limit public exposure to toxic pollutants in drinking water; and
— an FDA rule establishing requirements for the safe handling of seafood in commercial processing operations.

Moreover, and this point bears emphasis, even rules that show a positive number in the benefits column have had whole categories of benefits excluded from the tally.

What is going on? Again, the answer requires careful understanding of what benefits are included and excluded in the underlying cost-benefit tabulation. It turns out that this study, with a few narrow and limited exceptions, again has assigned a zero value to any benefit which the government's regulatory impact assessment does not quantify and monetize. It even zero-values benefits that are quantified and monetized in an agency RIA, unless they happen to fall into one of his select categories of recognized benefit—even as he insists that he is using the government's numbers.

Included, therefore, are benefits of reducing physical accidents, cancer, heart disease and a range of known ailments resulting from exposure to five named air pollutants. Zeroed out, however, are all ecological benefits not monetized by the agency. Also zeroed out are all benefits of avoiding acute poisoning—hence the zero value for rules aimed at avoiding acute pesticide poisoning and seafood poisoning. Also zeroed out are all procedural and enforcement benefits since they are intrinsically non-monetizable.

In short, the studies that purport to expose tunnel visioned over-zealousness in regulatory agencies—and the need for expanded OIRA review—have failed to make their case on the facts. Rather than illustrating the benefits of cost-benefit analysis in bringing clarity, transparency and rigor to regulatory analysis they expose the capacity of such analysis for concealing methodological icebergs and delivering skewed and misleading results. Far from establishing that OIRA oversight is needed to correct tunnel vision in the agencies, they simply suggest a dangerous tendency towards tunnel vision within OIRA itself.

It is true, of course, that cost-benefit analysis need not be done this way—it can be done in a way that does not over-ride inconvenient truths delivered by science, that is sensitive to qualitative costs and benefits, and that is properly cognizant of relevant uncertainties. Cost-benefit analysis can prompt regulations as well as embarrass them. And OIRA is not always anti-regulatory. Indeed, OIRA, under Mr.

Graham's leadership, has prompted a few quite valuable regulations that might not otherwise have been forthcoming, such as the trans-fat labeling rule.

Overall, however, it must be said that cost-benefit analysis in OIRA's hands—applied within the framework of E.O. 12866 and E.O. 13422—is generally not a particularly "fair and balanced" test. It is applied, for the most part, only to regulations and proposals to regulate—not to proposals to de-regulate or failures to regulate. It privileges quantity over quality, and numbers over judgment. It tends to conceal uncertainty behind the façade of a few summary statistics. It assumes, without basis, that maximizing monetary net benefits will also maximize social welfare—when economists themselves acknowledge that this assumption only holds if the losers from non-regulation or weak regulation are actually compensated by the winners, an event that in the real world very seldom happens. It takes as actual costs and benefits figures that are at best *ex ante* guesses—adopted in advance of regulation—as to what those regulatory costs and benefits are likely to be.

Moreover, we are now in a position to see that the cumulative cost-benefit analysis mandated by E.O. 13422 is the worst of the worst, methodologically. For even if you could manage to preserve some nuance—some attention to qualitative variables, dynamic effects, asymmetric uncertainties—in the analysis of individual rules, these nuances are completely squeezed out in the ringer of cumulative analysis. In cumulative cost-benefit analysis—as in regulatory scorecards—only summary statistics survive.

Meanwhile, applying OIRA review and cost-benefit analysis to guidance documents makes even less sense than applying it to proposed new rules, because guidance documents are very often adopted because the agency's knowledge of the facts is so limited that it feels it is not ready to propose a comprehensive rule. The purpose of guidance is to provide regulated entities some clarity while preserving some flexibility to change course and make exceptions when the facts of a particular case reveals that the policy is wrong. By encumbering guidance, E.O. 13422 will either deter it (thereby impeding clarity) or else ossify it, thereby hampering flexibility. And the uncertainty that often calls forth guidance documents—as opposed to rules—in the first place, does not augur well for the application of cost-benefit analytical techniques to guidance.

Let me conclude on a more affirmative note by asking what then should be done? I have challenged the evidence and analysis under-girding studies which purport to show that regulatory agencies are pervasively irrational and biased in favor of unreasonably costly regulation. That said, I certainly do not maintain that agency regulation is pervasively rational, on any plausible definition of that term. I have not proved that, and I readily concede that I cannot prove it. The question, I submit, is an open one.

I expect that what careful investigation would show is that agencies vary. Some favor industry, others favor regulatory beneficiaries. Moreover, their slant changes over time, depending on who occupies the White House and the front office and that agency. Agency predilections may even vary from office to office and from rule to rule. On balance, I expect the evidence will show that under-regulation is as much a problem as over-regulation—an insight that Mr. John Graham evidently shares. But I also conclude that quantitative cost-benefit analysis as *currently practiced* in OIRA and by its chief outside supporters is more contributor to that problem than cure—a stance he most emphatically does not share.

But all this is speculation. What is needed both to resolve this speculation and to improve agency regulation, I argue, is not more quantitative cost-benefit analysis and ever expanding OIRA review of first rules and now guidance. That is the wrong path and the wrong direction. The right way is, first, to undertake some strategically targeted retrospective analyses of the actual costs and benefits of actual rules to provide a "ground truth" of how accurate, if at all, *ex ante* analysis has been in a variety of regulatory situations, and to reveal the kinds of hitherto unanticipated factors that may arise to defeat *ex ante* expectations.

Second, agencies might be asked to engage—not OIRA—but relevant experts and the public more fully in the development of guidance documents. One might imagine an abbreviated consultation process commensurate with the magnitude of the guidance issues and their difficulty of resolution which agencies might be asked to undertake to better guide their guidance. The advent of the Internet makes such a process not only conceivable but easy to imagine and design, and OIRA might well apply its energies to working with agencies to develop such a process—remembering also that guidance is intrinsically tentative.

Finally, agencies should think about exploring innovative ways to harness the power of the Internet to make rule-making more expert, more participatory and more efficient. The Administrative Law Section of the ABA has undertaken a project on e-rule-making, and while none of the views expressed here today should be at-

tributed to the participants in that project, I think I can say with conviction that all of us in the project would be happy to work with OIRA, with public interest groups, regulated entities and not least the members of this committee and their staff in a collaborative effort to achieve wiser rules by improving the rule-making and guidance development process.

Thank you for the opportunity to address you today. I would be happy to try to answer any questions you might have.

BIOGRAPHY FOR RICHARD W. PARKER

Professor Parker has studied and taught administrative and environmental law—and regulatory policy—for over a decade; published articles in leading scholarly journals on the subject of OIRA review and the use of cost-benefit analysis; and benefited from sustained participation in work of the Administration Law Section of the ABA, where he has co-chaired both the Regulatory Policy Committee and the Committee on e-rule-making. He also has served as Special Counsel to the Deputy Administrator of EPA and as Assistant General Counsel of USTR. He holds a B.A. from Princeton University, a J.D. from Yale Law School, and a D.Phil. in Politics from Oxford University, which he attended as a Rhodes Scholar.

DISCUSSION

MORE ON REGULATORY POLICY OFFICERS

Chairman MILLER. Thank you. I want to ask Professor Strauss questions early because I understand he may need to leave but I wanted to ask first a question of Dr. Bass because part of his testimony addressed some issues I have been thinking about myself.

You discussed a reporting requirement to show what proposed rule-making was presented to an RPO and the RPO said no or adjusted what went forward, who talked, who was involved, all the things that Mr. Rohrabacher seemed to think were suggesting sinister motives, but just in the interests of transparency it doesn't seem unreasonable to know what agencies of government, what they are deciding, why they are deciding it and who is involved. But you suggested it be once a year. Why that infrequently? It seems like many of these decisions if they are to be challenged, a decision not to go forward with rule-making, if that is to be challenged, it should be challenged much more quickly than once a year. You could easily have an 11-month period. Dr. Bass.

Dr. BASS. Well, I completely agree with you, Mr. Chairman, and in my haste to speedily move through an oral statement I mushed together many items, and that is a technical term, mushed. I do think that what needs to happen is, there needs to be a proper record established at the agency so that these RPOs are held accountable, and that would mean ongoing review. What I was suggesting to help the public is through the twice-a-year Unified Regulatory Agenda that is published in the *Federal Register,* there should be a section on items that were permitted to go forward, items that were not permitted to go forward, and a justification why. The annual report should go to Congress and you may seek to have it even more often, but that annual report should also get into what changes in those that were going forward, what changes were proposed in going forward along with the documentation from the civil service staff that was transmitted to the RPO so that you have a record of all of that, and let me just say, what we are talking about, Mr. Chairman, is mini OIRAs. Through this RPO system and the connection of the RPO to OIRA creates the equivalent of

an OIRA on steroids, so it is essential to do what you are saying and I realize it is a burden for the agencies and I realize we are running up against things but it is essential.

Chairman MILLER. Professor Strauss, you raised great concerns about the statutory authority for RPOs to be given the powers that they are. What remedies do you see that are available to Congress for RPOs to be acting beyond the powers that Congress thought we were giving agencies or the executive branch in rule-making? What can we do about it?

Mr. STRAUSS. This is a complex question in the world of politics as well as law because of course Congress doesn't act alone and what you are talking about is a measure in which the President has a significant and I would say personal political interest so that whatever Congress might decide to do, either has to meet the President's willingness or you have to be able to do it in a fashion that he can't resist over—you have to be able to override a presidential veto or perhaps you have to do it in some form where he is obliged to accept the whole package, and this bit of remedy goes with it. I would suppose that if Congress were to come to the conclusion that regulatory policy officers had been authorized to do things that Congress had not authorized them to do and Congressional permission was necessary, one straightforward thing to do would be to provide in the annual budget no funds could be expended for these inappropriate functions. That is a kind of measure that is frequently found in other contexts in appropriations measures that the President signs on to. He wouldn't like it. I don't think that is very good legislating in an important way but you are between a rock and a hard place, it seems to me, and what I imagine might result from this would be some negotiations between the White House and the Congress in which one could come to an understanding about how the regulatory policy officers would function including provisions for transparency. This has been the history of Executive Order 12866 and its predecessors. It has been the regular course of bargaining over time between Congress and the White House. The transparency provisions currently in 12866 did not get there by accident. They were very much the product of Congressional prodding in the period leading up to the adoption of Executive Order 128666 under the Reagan executive order then administered by President Bush. It had got to the point where Congress refused to confirm a director of OIRA for a period of years on the understanding that we were going to have some bargains made about the way in which you exercise this authority, and those bargains were made.

MORE ON SEPARATION OF POWERS AND MARKET FAILURE PROVISIONS

Chairman MILLER. My time has expired. It is my turn again.

Professor Strauss, yes, I would imagine that that would be the subject of bargaining but I have yet to see much bargaining. You saw some of it in the first panel when the witness said that this executive order was designed to enhance transparency and I said how did you decide that? He said it is none of your business. Certainly withholding funds, as you point out, is not the best way for Congress to impose its will to just prevent the President from au-

thorizing something but politics as they are, that is possible and that is certainly one thing that may be possible.

A question for anyone on the panel who wishes to address it, I raised questions in my opening remarks about the criteria that were in this executive order for issuing orders or particular remedies, particular regulations, market failure and then some elaboration of what constitutes market failure. Does that criterion appear in statute, and if it does not, what is the authority of the executive branch to add that as a criterion in issuing regulations?

Mr. STRAUSS. Well, I am not sure that this will be a wholly satisfactory response. In part in response to Congress's own wish to have this information, the President requires cost-benefit analysis to be done in accordance with the criteria that he has in mind, I don't myself find any difficulty with his asking for agencies to do that analysis. It can be helpful to the President in proposing legislation, in pursuing the priorities of his Administration. It can be helpful to the Congress in understanding where legislation may or may not be needed, and at least if honestly done, I really do commend my colleague Parker's extended studies for their demonstration of how poorly cost-benefit analysis is sometimes done in the service ultimately of political ends. But if it is well done, it is an informative and useful means of analysis. For me, the difficulty comes, and I think this is instinct in your question, when one moves from acquiring information from consulting with agencies that the President is unquestionably entitled to do, to taking over decisions, to telling agencies specifically what they are to do. When you pass statutes, you give agencies responsibilities and you give agencies responsibilities within specific parameters. Not so recently, the Supreme Court made very clear, for example, that for the EPA, costs are not part of the statutory equation. It doesn't mean that EPA can't develop for the White House information about costs and even have discussions with the White House in which the White House's view about the importance of avoiding excessively costly regulations may be an element of the discussion, but the responsibility for decision is placed in EPA's hands and EPA is not entitled when making or explaining its decision to consider costs. It is quite straightforward as a matter of law. So the issue is not so much not having the analyses made as making clear where it is that the responsibility for decision lies and that decisions have to be taken without regard to these statutorily inappropriate factors.

Chairman MILLER. Mr. Parker.

Mr. PARKER. Yeah, and I just would add that I think with regard to your specific question about market failure, whether or not this new language is problematic I think would depend a lot on how it is implemented. For example, any good lawyer I think who wants to justify a regulation could within very broad bounds identify a market failure that the regulation could address. Market failures abound around us. It is pretty low-hanging fruit. And there is also a savings clause in case you can't do it. But the regulation itself on its face is not facially problematic. The question is whether this signals an intent for OMB to come back and start engaging in a rebuttal process, a dialog and debate about whether there really is this market failure, how bad is the market failure, would the mar-

ket failure be as bad as possible government failure, which is a standard, you know, conservative anti-regulatory—and if that is what this—if that is the intention behind this language change, then that is distinctly problematic. The language change itself, if market failure is an explanation that needs to be made and can be made unilaterally by the agencies and is taken by everybody outside, that would cause no problem to me. It is this question about whether it becomes a debating issue.

Dr. BASS. If I could add just——

Chairman MILLER. Dr. Bass.

Dr. BASS.—three more points to the fine and important comments from my colleagues. One is, I know of nothing in cross-cutting law that requires a market failure analysis. There may be specific requirements in individual statutes but there is nothing to my knowledge that addresses this, which raises a question about again the separation of powers question that you have been raising all day of Congressional authority versus executive-branch authority. The second point is that what has not been mentioned about market-failure criteria today, Mr. Aitken failed to mention that one of the changes in the new executive order is the last line which is an assessment of whether any new regulation is warranted. That becomes dangerously close to what Professor Strauss was talking about as being determinative, and if this rises to the level of that, then this is extremely troubling. The third point is confusion. Agencies have to implement this in a few months. What the heck is market-failure assessment supposed to involve? What we heard today is a repeat of three criteria that are simply listed in the new executive order. That doesn't help me clarify what it means to happen. It could be as absurd as the fact that the OIRA administrator, Susan Dudley, drives a hybrid. Is that an indicator there is no problem with climate change? I mean, I don't know what a market-failure assessment will involve and the agencies are left holding the bag now.

Chairman MILLER. I am not a witness here but I agree with Dr. Parker's assessment that there probably is a role for something—is the market going to take care of this, are we fixing something that really is not broken—and in deciding whether to issue new regulations, whether to address a problem by regulation. If there is a problem that is going to work itself out fairly shortly, fairly easily, there probably should be some discretion but as Professor Parker points out, it is a criterion that lends itself to seeing everything through a dogmatic lens and there is a philosophical point of view that the market fixes everything, the market never fails, and that is the point I made in my opening remarks, or in an earlier round of questioning, rather. That was the debate last week. That will be the debate again and again on every issue where Congress is proposing anything new: is the market going to fix it if Congress will leave it alone. And obviously when we act in the face of that, we are rejecting the argument that the market has not failed, the market will fix it on its own, which does make I think transparency all the more important. When is that criterion being applied, how is it being applied, so that someone may challenge it. If someone wishes to bring a lawsuit to say the agency should have acted and did not, that they know when it is happening, and I think all of

you have made that transparency point in your testimony and it is an issue that I raised in the last hearing on this topic.

MORE ON TRANSPARENCY PROVISIONS

Professor Strauss, Professor Parker, you heard Dr. Bass's discussion of possible transparency fixes. Do you all have any thoughts on how we can address transparency issues?

Professor Strauss.

Mr. STRAUSS. I think that it would be useful, I am not sure it would succeed for the Congress to require OIRA and the agencies to follow what has in fact been the best practice, that I am aware of agencies under the executive order as it now is. The Department of Transportation, as you may know, has a really quite terrific docketing system for all of its rule-makings into which every scrap of paper that they may get is either scanned, or if it is in electronic form, dumped, and if one looks at those dockets for the Department of Transportation, one finds accounts of the meetings with OIRA that are thorough and extensive, who was there, what did they say, what did the government officials say. That is done at the Department of Transportation. As it happens, they have been running a particularly efficient and effective rule-making process that probably not coincidentally runs into trouble with the courts a lot less than the rule-making making processes in other agencies. That should happen universally. OIRA doesn't keep the Department of Transportation from making these transcripts available on its web site. I don't imagine that it would be resisted as a general matter but OIRA isn't enforcing that either.

Chairman MILLER. Professor Parker.

Mr. PARKER. Yes. I would second that, and the suggestion of the people in the agencies who made the complaint that I reported was that an instruction be put out that basically is somewhat like the instruction that is there now but extended into the pre-regulatory initiative process and I think that is what DOT is already doing. So it can be done. And I would also just offer a comment on the anticipated rebuttal, which is that all of this would get into the deliberative process and we can't do that. It is ironic that first, the Department of Transportation is doing it. Second, I thought it was interesting that the OMB in this new executive order seems to be favoring or encouraging formal rule-making, something we haven't really talked about, and actually exempting OIRA review from processes to go through formal rule-making. What formal rule-making is, you know, even though it is too cumbersome to be really workable because of its trial provisions, it does have one provision involving ex parte contacts, which is a ban on them once things have initiated, which is directly relevant here and I think it gives a pretty good answer to arguments that oh, we must have all of these things, you know, in back rooms or people won't be able to be candid. You know, in that process, things are put on the record and we don't consider that a faulty or a hampered or an impaired decision process because everything has to take place on the record. So I think that there are answers to that and I think the solution that Professor Strauss echoed is a good one.

Dr. BASS. Mr. Chairman, could I just add one more element to this?

Chairman MILLER. Dr. Bass.

Dr. BASS. Ultimately, we always have to keep in mind why regulations are needed. We are first and foremost about protecting the public and our natural resources, and we tend to get lost in the discussion of the technicalities of the rule-making system and forget about the end objective. In that context, transparency is critically important, and I also think that this committee and other committees in Congress really need to look at the panoply of analyses imposed on the agencies. This market-failure criterion is yet another one. Dr. Melberth testified in your first hearing about a range of requirements that agencies have, what many call paralysis by analysis or Professor McGarity has called ossification. We have to look at that in the context of our objective to get speedy, responsive regulation done. Ultimately, what has happened and is so central to what you are chairing here is we find time and again now politics is superseding science, and the only way I know to address that is to talk about the entire regulatory process as something that needs to be opened up. That is why the guidance issue that has come up in this context of the executive order is troubling. If more agencies are turning to guidance, it is probably because the existing rule-making system doesn't work that well from their point of view. It is then subjected to the same system. We are kind of going around in circles on this issue.

Mr. STRAUSS. If I could just add one thought to that. The formal rule-making provision is an invitation to another form of paralysis by analysis and presumably this is the reason why the OIRA process is not regarded as being so important there. What it does is, it delivers into the hands of those who would wish to obstruct rule-making making the procedural tools with which to do so through cross-examination, through extended processes and the like. This is why it is not used anymore is because it is a terribly inefficient means to make rules. But I do want to echo what Mr. Bass has said. One job for the Congress, perhaps not your committee but another, clearly is to take the enormous range of provisions that have been adopted by executive order and by legislation requiring analysis of this issue and that issue and this other issue in the course of rule-makings and to produce a somewhat more streamlined version. I don't think that is our work today but it is a matter of enormous importance to the success of this mechanism.

Chairman MILLER. I think that is all the questions that I have for now. Do any of you have any valedictory comments, Professor Parker, Dr. Bass, Professor Strauss?

Dr. BASS. We appreciate you holding this hearing.

Chairman MILLER. Thank you very much for being here. Our hearing is adjourned.

[Whereupon, at 1:20 p.m., the Subcommittee was adjourned.]

Appendix:

Additional Material for the Record

Order Code RL33862

CRS Report for Congress

Changes to the OMB Regulatory Review Process by Executive Order 13422

Updated February 21, 2007

Curtis W. Copeland
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Prepared for Members and Committees of Congress

Congressional Research Service

Changes to the OMB Regulatory Review Process by Executive Order 13422

Summary

Executive Order (E.O.) 12866 on "Regulatory Planning and Review," issued in September 1993, describes the principles and procedures by which the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) reviews hundreds of significant proposed and final agency regulations on behalf of the President before they are published in the *Federal Register*. On January 18, 2007, President George W. Bush issued E.O. 13422, making the most significant amendments to E.O. 12866 since it was published. The changes made by this new executive order are controversial, characterized by some as a "power grab" by the White House that undermines public protections and lessens congressional authority and by others as "a paragon of common sense and good government."

The most important changes made to E.O. 12866 by E.O. 13422 fall into five general categories: (1) a requirement that agencies identify in writing the specific market failure or problem that warrants a new regulation, (2) a requirement that each agency head designate a presidential appointee within the agency as a "regulatory policy officer" who can control upcoming rulemaking activity in that agency, (3) a requirement that agencies provide their best estimates of the cumulative regulatory costs and benefits of rules they expect to publish in the coming year, (4) an expansion of OIRA review to include significant guidance documents, and (5) a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases.

This report discusses each of these changes, noting areas that are unclear and the potential implications of the changes; provides background information on presidential review of rules; and discusses two February 2007 hearings on the executive order. It concludes by noting that the significance of the changes made to the review process by E.O. 13422 may become clear only through their implementation and notes some areas of potential congressional interest. The changes made by this executive order represent a clear expansion of presidential authority over rulemaking agencies. In that regard, E.O. 13422 can be viewed as part of a broader statement of presidential authority presented throughout the Bush Administration.

The report will be updated as necessary to reflect legislative or executive branch actions relevant to the implementation of the executive order.

Contents

Changes to the OMB Regulatory Review Process by Executive Order 13422

Executive Order (E.O.) 12866 on "Regulatory Planning and Review," issued by President William Clinton in September 1993, describes the principles and procedures by which the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA) reviews hundreds of significant proposed and final agency regulations on behalf of the President before they are published in the *Federal Register*.[1] As a result of these reviews, OIRA can have a significant — if not determinative — role in the development of a broad array of public policies, from the homeland security rules governing boarding of passenger aircraft to the amount of arsenic allowed in public water systems.[2]

On January 18, 2007, President George W. Bush issued E.O. 13422, making the most significant amendments to E.O. 12866 since it was published.[3] The changes made by this new executive order are controversial, characterized by some as a "power grab" by the White House that undermines public protections and lessens congressional authority,[4] and by others as "a paragon of common sense and good government."[5] This report describes the changes made to the regulatory planning and review process by the new order, noting the potential impact of those changes and areas that are unclear. It also describes two hearings in February 2007 examining the new executive order. The report ends by offering some concluding observations.

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[1] Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, Oct. 4, 1993.

[2] U.S. General Accounting Office, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews*, GAO-03-929, Sept. 22, 2003, p. 3, available at [http://www.gao.gov/new.items/d03929.pdf]. See also CRS Report RL32397, *Federal Rulemaking: The Role of the Office of Information and Regulatory Affairs*, by Curtis W. Copeland; and CRS Report RL32855, *Presidential Review of Agency Rulemaking*, by T.J. Halstead.

[3] Executive Order 13422, "Further Amendment to Executive Order 12866 on Regulatory Planning and Review," 72 *Federal Register* 2763, Jan. 23, 2007. Five years earlier, E.O. 13258 reassigned certain responsibilities from the Vice President to the President's chief of staff, but otherwise did not change the OIRA review process. See Executive Order 13258, "Amending Executive Order 12866 on Regulatory Planning and Review," 67 *Federal Register* 9385, Feb. 28, 2002.

[4] Public Citizen, "New Executive Order Is Latest White House Power Grab," available at [http://www.citizen.org/pressroom/release.cfm?ID=2361].

[5] Attributed to William Kovacs, Vice President of Environment, Energy, and Regulatory Affairs, U.S. Chamber of Commerce, in John Sullivan, "White House Sets Out New Requirements for Agencies Developing Rules, Guidance," *Daily Report for Executives*, Jan. 19, 2007, p. A-31.

First, though, the report provides a brief background section on the regulatory planning and review procedures established by E.O. 12866 and its predecessors.

Regulatory Planning and Review Under E.O. 12866

Centralized review of agencies' regulations within the Executive Office of the President has been an important part of the federal rulemaking process for more than 35 years. Although each of his three predecessors had some type of review process, the most significant development in the evolution of presidential review of rulemaking occurred in 1981, when President Ronald Reagan issued E.O. 12291.[6] The executive order established a set of general requirements for rulemaking, and required federal agencies (other than independent regulatory agencies) to send a copy of each draft proposed and final rule to OMB before publication in the *Federal Register*.[7] It also required covered agencies to prepare a cost-benefit analysis for each "major" rule (e.g., those with at least a $100 million impact on the economy). As a result of this order, OIRA became the central clearinghouse for covered agencies' substantive rulemaking, reviewing between 2,000 and 3,000 rules per year. In 1985, President Reagan expanded OIRA's influence further by issuing E.O. 12498, which required each covered agency to submit a regulatory plan to OMB for review each year that covered all of their significant regulatory actions underway or planned.[8] Regulatory reviews under these executive orders were highly controversial, with complaints about the lack of transparency of the review process, unlimited delays in the completion of the reviews, OIRA serving as a conduit for influence by regulated parties, and executive branch displacements of congressional delegations of rulemaking authority.[9]

On September 30, 1993, President Clinton issued E.O. 12866, which revoked E.O. 12291 and E.O. 12498 and established a new process for OIRA review of rules. The order limited OIRA's reviews to actions identified by the rulemaking agency or OIRA as "significant" regulatory actions, defined as those that were "economically significant" (e.g., those with at least a $100 million impact on the economy) or that (1) were inconsistent or interfered with an action taken or planned by another agency; (2) materially altered the budgetary impact of entitlements, grants, user fees, or loan programs; or (3) raised novel legal or policy issues. As a result of this change, the number of rules that OIRA reviewed dropped from between 2,000 and 3,000 per year to between 500 and 700 per year. For each significant draft rule, the executive order

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[6] Executive Order 12291, "Federal Regulation," 46 *Federal Register* 13193, Feb. 19, 1981.

[7] Independent regulatory agencies include the Federal Communications Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission, and are created by Congress to be more independent of the President than other agencies (e.g., commission members may generally be removed by the President only for cause).

[8] Executive Order 12498, "Regulatory Planning Process," 50 *Federal Register* 1036, Jan. 8, 1985.

[9] See, for example, Morton Rosenberg, "Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12291," *Michigan Law Review*, vol. 80 (1981), pp. 193-247.

requires the issuing agency to provide to OIRA the text of the draft rule, a description of why the rule is needed, and a general assessment of the rule's costs and benefits. For draft rules that are "economically significant," the executive order requires a detailed cost-benefit analysis, including an assessment of the costs and benefits of "potentially effective and reasonably feasible alternatives to the planned regulation."

E.O. 12866 also differs from its predecessors in other respects. For example, the order requires that OIRA generally complete its reviews of proposed and final rules within 90 calendar days. It also requires both the rulemaking agencies and OIRA to disclose certain information about how the regulatory reviews were conducted. For example, agencies are to identify for the public (1) the substantive changes made to rules between the draft submitted to OIRA for review and the action subsequently announced, and (2) changes made at the suggestion or recommendation of OIRA. OIRA is required to, among other things, provide agencies with a copy of all communications between OIRA personnel and parties outside the executive branch, and to maintain a public log of all regulatory actions under review and of all the documents provided to the agencies. Finally, E.O. 12866 required all agencies (including independent regulatory agencies) to prepare a regulatory plan listing the most important regulatory actions that the agency expects to issue in the next fiscal year. Agency heads were required to approve this plan personally.

Changes Made by E.O. 13422

The most important changes made to E.O. 12866 by E.O. 13422 fall into five general categories: (1) a requirement that agencies identify in writing the specific market failure or problem that warrants a new regulation, (2) a requirement that every agency head designate a presidential appointee within the agency as a "regulatory policy officer" who can control upcoming rulemaking activity in that agency, (3) a requirement that agencies provide their best estimates of the cumulative regulatory costs and benefits of rules they expect to publish in the coming year, (4) an expansion of OIRA review to include significant guidance documents, and (5) a provision permitting agencies to consider whether to use more formal rulemaking procedures in certain cases. Each of these changes is described more fully in the following sections.

Identification of Market Failure

E.O. 12866 begins with a statement of regulatory philosophy and principles that sets the tone for agency rulemaking covered by the order. The principles say that, "to the extent permitted by law and where applicable," agencies should (among other things) assess alternatives to direct regulation, design regulations in the most cost-effective manner possible, and base regulations on the best information available. As originally written, the first such principle was that "[e]ach agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem."

E.O. 13422 changes that language somewhat, stating the following:

> Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.

The new language appears to (1) elevate "market failure" to greater prominence as a rulemaking rationale (removing the "where applicable" caveat and placing it before and on par with the more general statement of problem identification); (2) more clearly define what constitutes a market failure (e.g., "externalities, market power, lack of information");[10] (3) require a more precise delineation of why the agency is issuing the rule (the "specific" market failure or the "specific" problem); (4) require that the delineation be in writing; and (5) make clear that the purpose of this requirement is to facilitate a determination of whether the rule is needed.

The general principle that a covered agency describe the need for a new regulation is procedurally established in Section 6 of E.O. 12866. For rules that are significant, but not economically significant (e.g., do not have a $100 million impact on the economy), agencies are required only to provide a "reasonably detailed description of the need for the regulatory action." For economically significant rules, however, more detailed cost-benefit analyses are required. OMB Circular A-4 (which describes how those studies should be done) says agencies "should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy."[11] Therefore, the "market failure" language in E.O. 13422 can arguably be read to apply to all significant rules (between 500 and 700 per year) what had previously applied only to economically significant rules (about 70 per year).

Also, although the order requires agencies to make this determination in writing, E.O. 13422 does not indicate where this written determination should appear (e.g., in the *Federal Register* notice for the proposed or final rule), or, additionally, whether it should be made available to the public in the rulemaking docket. Conceivably, therefore, agencies could satisfy the requirements of the order by preparing a written determination of the need for a rule without providing it to anyone outside government.

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[10] According to OMB Circular A-4, an "externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods." It says "[f]irms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices," such as when a monopoly exists. Inadequate information can occur when the public is unaware of the dangers associated with the use of a product. To view a copy of this circular, see [http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf].

[11] To view a copy of this circular, see [http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf].

Some commentators have criticized this provision in E.O. 13422 as an attempt to bypass Congress by establishing standards for regulatory initiation that are not consistent with statutory requirements. One such commentator, Public Citizen, said the requirement "diminishes standards Congress may have required agencies to use, such as the best control technology, by elevating a new market failure standard that Congress never required."[12] For example, some statutes (e.g., the Clean Air Act) require agencies to establish regulations based solely on what is required to protect human health. Critics of the executive order contend that requiring agencies to identify a "specific market failure" or a "specific problem" constitutes a new standard for regulatory initiation. Supporters of this provision contend, however, that market failure is not the only basis on which regulatory agencies can justify action, and that the executive order did not eliminate the requirement in E.O. 12866 that directs agencies to issue "such regulations as are required by law, [or] are necessary to interpret the law."[13]

Public Citizen has also criticized this provision as "yet another layer added to the agency analysis" that "places yet another hurdle for agencies to issue regulations in pursuit of protecting the public." Similarly, Gary Bass, executive director of OMB Watch, said that President Bush, by requiring agencies to show a market failure, "has created another hurdle for agencies to clear before they can issue rules protecting public health and safety."[14] On the other hand, supporters of this provision contend that requiring agencies to identify the specific problem being addressed in a regulation is not onerous, and can help ensure the effectiveness of the resultant rules.[15]

Finally, although stated in terms of a requirement ("[e]ach agency shall"), this and other principles of regulation in the executive order are preceded by more permissive language, stating that agencies "should" adhere to the principles "to the extent permitted by law and where applicable." Given this language, concerns about the usurpation of congressional standards for rulemaking and unnecessary delay may be exaggerated. Ultimately, though, the extent to which these changes are significant may be revealed only through how they are implemented by OIRA and the agencies.

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[12] Public Citizen, "New Executive Order Is Latest White House Power Grab."

[13] Testimony of Steven D. Aitken in U.S. Congress, House Committee on the Judiciary, Subcommittee on Commercial and Administrative Law, *Changes to OMB Regulatory Review by Executive Order 13422*, Feb. 13, 2007, available at [http://judiciary.house.gov/media/pdfs/Aitken070213.pdf].

[14] Robert Pear, "Bush Directive Increases Sway on Regulation," *New York Times*, Jan. 30, 2007, p. A1.

[15] Testimony of Paul Noe in U.S. Congress, House Committee on the Judiciary, Subcommittee on Commercial and Administrative Law, *Changes to OMB Regulatory Review by Executive Order 13422*, Feb. 13, 2007, available at [http://judiciary.house.gov/media/pdfs/Noe070213.pdf].

Regulatory Policy Officers as Presidential Appointees

As originally written, E.O. 12866 required the head of each covered agency (other than independent regulatory agencies) to designate a regulatory policy officer who reported to the agency head.[16] The policy officer is required to "be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order." According to agency officials, these regulatory policy officers were commonly agency general counsels (which are usually presidential appointees with Senate confirmation) or some other presidential appointee within the agencies.

E.O. 13422 retains the above general statement of the policy officer's duties, but also requires each agency head to "designate one of the agency's Presidential Appointees" to be that officer, to do so within 60 days of the date of the executive order (i.e., by March 19, 2007), to advise OMB of the designation, and to "annually update OMB on the status of this designation." Although the agency head is still permitted (within the parameters of White House and OMB control) to select the individual for this position, the requirement that the individual be a presidential appointee limits the agency head's discretion (compared to the unlimited authority that agency heads enjoyed before this amendment) and strengthens the relationship of the agency policy officers with the President. Because most of the regulatory policy officers are already presidential appointees, it is not clear how this requirement will affect the regulatory process. If agencies are permitted to continue with the same officers they have always had, then the effect may be minimal. On the other hand, if agency heads are required to designate new presidential appointees to serve in this capacity, then the effect may be more significant.

The new executive order also changes the regulatory policy officers' reporting relationship. Previously, E.O. 12866 required the policy officers to report to the agency heads who designated them; E.O. 13422 eliminated this requirement, but did not provide substitute language. Therefore, it is not clear to whom these presidential appointees would report.

E.O. 13422 also appears to significantly enhance the role of the agency regulatory policy officer as part of the regulatory planning process. The order states that "[u]nless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Office."[17] This change appears to represent an elevation in the

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[16] Although the regulatory planning sections apply more broadly, the executive order generally defines an "agency" as "any authority of the United States that is an 'agency' under 44 U.S.C. 3502 (1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502 (10)." The order does not define "agency head," but agency policy officers in Cabinet departments have typically been designated by the secretary.

[17] Notably, E.O. 13422 speaks in terms of a regulatory policy "office" as opposed to a regulatory policy "officer," suggesting that agencies may provide staff to assist the policy

(continued...)

duties and responsibilities of the agency policy officer when compared to the role previously ascribed to that officer (i.e., to "be involved" in the regulatory process, to "foster the development" of sound rules, and to "further" the order's principles). Unless specifically authorized by the agency head, the presidential policy officer must approve the listing of all significant forthcoming regulatory actions in the regulatory plan and approve the initiation of all rulemaking actions. (Previously, only the agency head could approve the regulatory plan, and there was no language in the order prohibiting rulemaking in the absence of the regulatory policy officer's approval.) As characterized in the *New York Times*, "[t]he White House will thus have a gatekeeper in each agency to analyze the costs and the benefits of new rules and to make sure the agencies carry out the president's priorities."[18]

The executive order's use of the word "designate" suggests that agency heads must select regulatory policy officers from among current presidential appointees within the agencies. (Neither the President nor agency heads are authorized to create presidential appointee positions; only Congress can do so.) The order is silent as to whether the designated presidential appointee would be subject to Senate confirmation. Senate confirmation of presidential appointees is generally considered a way to strengthen congressional influence over agency decision making, because (among other things) nominees often agree during the confirmation process to appear subsequently before relevant congressional committees. According to the most recent listing of "Policy and Supporting Positions" (known as the "Plum Book"), most major regulatory departments and agencies have few (and in some cases, no) presidential appointees who are not Senate confirmed.[19] Therefore, in most cases, agency heads must select presidential appointees who are subject to Senate confirmation.[20]

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[17] (...continued)
officers in their duties within the agencies. However, the acting OIRA Administrator has said that "office" was a typographical error, and should have said "officer."

[18] Robert Pear, "Bush Directive Increases Sway on Regulation." Newspaper editorial writers have offered various opinions regarding this issue. For example, see David McNaughton, "Reverse Regulation: With Another Nonsense Order, President Bush Quashes Legitimate Rule-making by Inserting Political Overseer," *The Atlanta Journal-Constitution*, Feb. 2, 2007, p. A10, which cited Emory University Law Professor William Buzbee as saying that this provision "makes it even more likely that regulatory decisions will be made by someone more sympathetic to political pressure and ideology than to the federal agency's legal duty." Also, see Jim Wooten, "Vouchers, Transit Alert, Sen. Obama," *The Atlanta Journal-Constitution*, Feb. 2, 2007, p. A11, which approved of this provision and said "[t]here's nothing radical about applying cost-benefit analysis to proposed laws and regulations."

[19] U.S. Congress, House Committee on Government Reform, *United States Government Policy and Supporting Positions*, Nov. 22, 2004. For example, the Department of Transportation had 32 positions subject to presidential appointment with Senate confirmation (PAS positions) in 2004, but none without Senate confirmation (PA positions). The Environmental Protection Agency had 14 PAS positions, but no PA positions; the Department of Labor had 19 PAS positions, but no PA positions. On the other hand, the Department of Homeland Security had 18 PAS positions, but also had six PA positions. .

[20] At a Feb. 13, 2007, hearing on E.O. 13422, the acting OIRA administrator confirmed that (continued...)

Even in agencies with presidential appointees who are not subject to Senate confirmation, one could argue that it is up to Congress to decide whether the position of regulatory policy officer should be occupied by an appointee who is Senate confirmed. The Supreme Court has held that "any appointee exercising significant authority pursuant to the laws of the United States is an 'Officer of the United States,' and must, therefore, be appointed in the manner prescribed" in the Constitution.[21] Given the enhanced power and authority of the policy officer to control day-to-day rulemaking activities within federal agencies ("no rulemaking shall commence"), the policy officer could be considered an officer of the United States under the appointments clause of the Constitution. Article II, Section 2, clause 2 of the Constitution states the following:

> [The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

Therefore, one could argue that it is the role of Congress to prescribe, in law, whether the regulatory policy officer position should be subject to Senate confirmation. In fact, to take this argument further, even if the agency head designated a person in a Senate-confirmed position for this new position, one could argue that this person would have to undergo another confirmation process because the scope of the person's responsibilities had been changed significantly.

One other element of this process is also unclear, and may represent a change in the scope of presidential influence in rulemaking. As noted previously, the requirement that each agency head appoint one of the agency's presidential appointees as the regulatory policy officer does not apply to independent regulatory agencies. However, E.O. 12866 requires independent regulatory agencies to develop regulatory plans, and the requirement in E.O. 13422 that the "Regulatory Policy Office" approve items included in the plan and the commencement of all rulemaking amends that section of E.O. 12866. Therefore, this provision could arguably be read to require that independent regulatory agencies have presidential appointees as regulatory policy officers, which would extend the reach of the President and presidential review into agencies that had not previously been subject to such scrutiny (and commensurately lessening the agencies' relationships with Congress, which created them).

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[20] (...continued)
most regulatory policy officers are Senate-confirmed presidential appointees. For a copy of his testimony, see
[http://www.whitehouse.gov/omb/legislative/testimony/oira/aitken_02132007.pdf].

[21] *Buckley v. Valeo*, 424 U.S. 1, 126 (1976).

Estimate of Aggregate Regulatory Costs and Benefits

As part of the above-mentioned regulatory planning process, agencies have been required to provide a "summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits." E.O. 13422 adds to this provision the requirement that each agency provide its "best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities."

At first impression, the changes established by this provision appear relatively straightforward, simply requiring agencies to tally up the costs and benefits of the individual rules listed in the regulatory plan. However, upon closer examination, some aspects of this provision appear unclear. For example, the regulatory plans that agencies develop are supposed to be published at the start of each fiscal year in October, and are required to reflect the most significant proposed and final rules that they expect to publish "in that fiscal year or thereafter." Therefore, the requirement in E.O. 13422 that agencies develop estimates of aggregate costs and benefits for regulations planned "for that calendar year" seems inconsistent with the previous focus on fiscal years.

More substantively, some critics of the order have suggested that this provision is intended to elevate the role of cost-benefit analysis in the development of regulatory priorities. They argue that cost-benefit analysis is inherently biased against regulation, particularly with regard to such issues as global warming and long-term exposure to carcinogens, so the effect of this provision would be to reduce regulatory activity.[22] Other critics have said this provision is a prelude to the development of a regulatory budget in which the costs associated with an agency's rules could be capped and no new rules could be issued unless other costs were reduced or eliminated.[23] Proponents of this provision, on the other hand, may argue that such aggregate estimates are needed to reveal the cumulative impacts of rulemaking. Individually, regulations on a particular industry may not be significant, but the aggregation of the impact of multiple rules may reveal cumulative effects that are not otherwise apparent.

Also, agencies' regulatory plans are published as part of the *Unified Agenda of Federal Regulatory and Deregulatory Actions*, and contain information about the most significant regulatory actions that agencies expect to undertake in the coming year.[24] The listed items include both proposed and final rules that the agency expects to issue during that period. For forthcoming proposed rules, agencies often have not

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[22] Public Citizen, "New Executive Order Is Latest White House Power Grab."

[23] OMB Watch, "Undermining Public Protections: Preliminary Analysis of the Amendments to Executive Order 12866 on Regulatory Planning and Review," available at [http://www.ombwatch.org/article/articleview/3685/1/132?TopicID=3].

[24] To view the most recent regulatory plan (published in December 2006), see [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2006_unified_agenda_&docid=f:ua061002.pdf].

developed cost or benefit estimates because the specifics of the proposed rules have often not been developed. Even for forthcoming final rules, agencies frequently provide only general narrative information about expected costs or benefits. Also, some items that are listed in agencies' regulatory plans are never issued as final rules, and some significant agency rules never appear in agencies' regulatory plans. Therefore, the requirement in the executive order that agencies provide aggregate cost and benefit information may prove difficult to implement in a meaningful fashion. On the other hand, as noted previously, agencies are only required to develop rule-specific and aggregate estimates of costs and benefits "to the extent possible." It is unclear whether the agencies or OIRA will ultimately determine what is "possible."

OIRA Review of Significant Guidance Documents

Another controversial provision in E.O. 13422 has been the expansion of OIRA review from agencies' draft regulations to also include significant agency guidance documents.[25] Specifically, the new executive order adds the following to E.O. 12866:

> Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notification of any significant guidance documents. Each agency shall take such steps as are necessary for its Regulatory Policy Officer to ensure the agency's compliance with the requirements of this section. Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before the issuance of the significant guidance document.

E.O. 13422 defines a "guidance document" as "an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue." It says a "significant" guidance document is one that is

> disseminated to regulated entities or the general public that, for purposes of this order, may reasonably be anticipated to:
>
> (A) Lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition,

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[25] On the same day that E.O. 13422 was issued, OMB also issued a "Final Bulletin for Agency Good Guidance Practices" that mirrored, in many respects, the provisions in this section of the executive order. Unlike the order, however, the bulletin requires agencies to include certain standard elements in their significant guidance documents, to list those documents on the agencies' websites, and to publish a notice in the *Federal Register* soliciting public comments on economically significant documents. To view a copy of this bulletin, see [http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf]; and Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," 72 *Federal Register* 3432, Jan. 25, 2007.

> jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
>
> (B) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
>
> (C) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or
>
> (D) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

These categories are essentially the same as those used in E.O. 12866 to define significant rules, the only difference being the use of the prefatory phrase "may reasonably be anticipated to" instead of "is likely to result in a rule that may."

The implications of these amendments to the scope of presidential review of agency actions are potentially significant. Agencies issue thousands of guidance documents each year that are intended to clarify the requirements in related statutes and regulations.[26] Therefore, the requirement that agencies provide OIRA with advance notification of significant guidance documents may represent a major expansion of the office's (and, therefore, the President's) influence, particularly when coupled with the ability of OIRA to determine which guidance documents are "significant" and the ability of OIRA to conclude that "additional consultation will be required" before a document is issued. Also, the requirement that presidentially appointed regulatory policy officers ensure compliance with this requirement arguably represents another extension of the President's authority in regulatory agencies.

As is the case with other aspects of E.O. 13422, though, several aspects of these provisions are unclear. For example, although the order refers to guidance "documents," the definition of the term is not limited to written materials. In a related OMB bulletin on agency guidance that was issued the same day as the executive order amendments, OMB said that the bulletin's definition of a guidance document (which is the same as in the executive order)

> is not limited only to written guidance materials and should not be so construed. OMB recognizes that agencies are experimenting with offering guidance in new and innovative formats, such as video or audio tapes, or interactive web-based software. The definition of "guidance document" encompasses all guidance materials, regardless of format.[27]

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[26] For example, the Occupational Safety and Health Administration indicated in 2000 that it had issued 3,374 guidance documents since March 1996. See U.S. Congress, House Committee on Government Reform, *Non-Binding Legal Effect of Agency Guidance Documents*, 106th Cong., 2nd sess., H.Rept. 106-1009 (Washington: GPO, 2000), p. 5.

[27] Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," p. 3434.

Therefore, a wide range of agency communications with the public — even oral statements by agency officials and staff — may be considered guidance "documents," as long as they are statements of "general applicability and future effect."

However, given the definition provided in the executive order, it is unclear what could constitute a "significant" guidance document. Guidance documents, unlike regulations, cannot have a binding effect on the public.[28] Therefore, it is not clear how guidance can be expected to have the effects delineated in the definition (e.g., "lead to an annual effect of $100 million or more" or "materially alter the budgetary impact" of entitlements or grants). Arguably, because no guidance document can, by itself, have such an effect, the requirement that agencies provide OIRA with advance notification of any significant guidance documents could have little or no impact on regulatory agencies. On the other hand, OMB has said that "there are situations in which it may reasonably be anticipated that a guidance document could lead parties to alter their conduct in a manner that would have such an economically significant impact."[29] Ultimately, because OIRA is given the authority to determine which documents are "significant," the scope and impact of this section's requirements may be as broad as OIRA determines that it needs to be.

Also unclear is the extent to which certain transparency provisions in E.O. 12866 will apply to guidance documents. For example, will agencies be required to disclose the changes to their significant guidance documents made at the suggestion and recommendation of OIRA (just as they are with regard to rules)? Will OIRA be required to list publicly the significant guidance documents that are under its review, and to disclose its meetings with outside entities regarding those documents? Because E.O. 13422 did not change those sections of E.O. 12866, it is reasonable to presume that the transparency provisions applicable to rules are not applicable to agencies' significant guidance documents.

Supporters of the expansion of presidential review to significant guidance documents have said the change will standardize and make more transparent the process by which federal agencies develop, issue, and use guidance documents.[30] Critics contend that the potentially broad scope of this provision may result in fewer guidance documents being issued, with the policy officer or OIRA review serving as a "bureaucratic bottleneck that would slow down agencies' ability to give the public information it needs."[31] Another possible effect of this requirement, given the number of guidance documents that agencies currently issue, is that OIRA staff may

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[28] See, for example, *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000); *Chamber of Commerce v. Department of Labor*, 174 F.3d 206 (D.C. Cir. 1999); Robert A. Anthony, "Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like — Should Agencies Use Them to Bind the Public?" *Duke Law Journal*, vol. 41 (1992), p. 1311.

[29] Office of Management and Budget, "Final Bulletin for Agency Good Guidance Practices," p. 3435.

[30] John Sullivan, "White House Sets Out New Requirements for Agencies Developing Rules, Guidance," citing Paul Noe, partner at C&M Capitolink, who was a counselor to former OIRA administrator John Graham.

[31] Public Citizen, "New Executive Order Is Latest White House Power Grab."

be inundated with such documents to review (on top of the hundreds of significant proposed and final rules and the thousands of paperwork clearances they produce each year) — at least until it is clear to the agencies what is and is not covered.

Use of Formal Rulemaking Procedures

E.O. 13422 also amends Section 6 of E.O. 12866 by adding the following sentence: "In consultation with OIRA, each agency may also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations." Virtually all agency regulations are currently issued under informal rulemaking procedures under 5 U.S.C. 553, in which agencies publish proposed rules in the *Federal Register* for public comment, and subsequently publish a final rule reflecting any changes made as a result of those comments. Formal rulemaking, as the name implies, is a much more rigorous, trial-like, on-the-record procedure in which interested persons testify and cross-examine witnesses, and the agency may take depositions and issue subpoenas. It is generally considered a more time-consuming and expensive process than informal rulemaking. Also, according to 5 U.S.C. 556(d)(1), "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." Formal rulemaking was criticized in the 1970s, and has fallen into disuse since then.[32] The Administrative Conference of the United States recommended that Congress should not require procedures beyond informal rulemaking, and should never require trial-type procedures for resolving questions of policy or fact.[33] One administrative law scholar has referred to formal rulemaking as a "discredited" procedure that allows regulated entities to slow down the rulemaking process.[34]

The executive order does not indicate, and OIRA has not explained, why this provision was added to E.O. 12866. Agencies have always had the ability to employ formal rulemaking when they conclude that it is in the agencies' best interest to do so. Therefore, the statement that agencies "may also consider whether to utilize formal rulemaking procedures" seems to grant discretion where discretion was already allowed. On the other hand, an agency's "consultation with OIRA" may result in greater use of formal rulemaking if OIRA can convince the agency that it is in their best interest to do so. If that occurs, agency rulemaking could become even more "ossified" than it already is.[35]

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[32] For a discussion of formal rulemaking, see Jeffrey S. Lubbers, ed., *A Guide to Federal Agency Rulemaking, Fourth Edition* (Chicago: American Bar Association, 2006), pp. 58-59.

[33] ACUS Recommendation 72-5, *Procedures for the Adoption of Rules of General Applicability*, 38 *Federal Register* 19782, 1972; Jeffrey S. Lubbers, ed., *A Guide to Federal Agency Rulemaking, Fourth Edition*, pp. 309-310.

[34] Testimony of Peter Strauss, Betts Professor of Law, Columbia Law School, in U.S. Congress, House Committee on the Judiciary, Subcommittee on Commercial and Administrative Law, hearing on Executive Order 13422, Feb. 13, 2007, available at [http://judiciary.house.gov/media/pdfs/Strauss070213.pdf].

[35] Several observers have commented on the "ossification" of the rulemaking process as a result of numerous statutory and executive order requirements. See, for example, Thomas

(continued...)

Congressional Hearings on E.O. 13422

On February 13, 2007, two House subcommittees held oversight hearings on Executive Order 13422 — one by the House Committee on Science and Technology's Subcommittee on Investigations and Oversight,[36] and the other by the House Committee on the Judiciary's Subcommittee on Commercial and Administrative Law.[37]

Subcommittee on Investigations and Oversight

At the Investigations and Oversight Subcommittee hearing, Chairman Brad Miller questioned whether the new executive order creates "an almost insuperable bias in favor of agency inaction," and whether the order "shift(s) to the President powers that the framers of our Constitution intended to be exercised by Congress." However, Ranking Member F. James Sensenbrenner, Jr. said "I am inclined to think that the issues that will be brought up today have less to do with their policy implications, and more to do with *who* issued them," and said he believed the executive order and the related OMB guidance bulletin simply formalize many of the principles established in previous administrations. (Emphasis in original.) Three of the four witnesses at the hearing noted areas of concern about the new executive order:

- Sally Katzen, a professor of law, OIRA Administrator during the Clinton Administration, and one of the original authors of E.O. 12866, noted three areas of concern about E.O. 13422: (1) its issuance "without any consultation or explanation," (2) its issuance "on the heels of OMB's imposing multiple mandates/requirements on the agencies when they are developing regulations," and (3) its effect of "making it more difficult for agencies to do their jobs because regulations are disfavored in this Administration."[38]

- David C. Vladeck, associate professor of law and director of the Institute for Public Representation at the Georgetown University Law Center, said the new order (1) "usurps congressional authority

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[35] (...continued)
O. McGarity, "Some Thoughts on 'Deossifying' the Rulemaking Process, *Duke Law Journal*, vol. 41 (June 1992), pp. 1385-1462; Richard J. Pierce, Jr., "Seven Ways to Deossify Agency Rulemaking," 47 *Administrative Law Review*, vol. 47, winter 1995, pp. 59-93; Paul R. Verkuil, "Rulemaking Ossification — A Modest Proposal," *Administrative Law Review*, vol. 47 (summer 1995), pp. 453-459.

[36] To view a copy of the hearing charter and the witnesses' prepared statements, see [http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=1269].

[37] To view this hearing and obtain copies of the witnesses' prepared statements, see [http://judiciary.house.gov/oversight.aspx?ID=269].

[38] For a copy of Ms. Katzen's written statement, see [http://democrats.science.house.gov/Media//File/Commdocs/hearings/2007/oversight/13feb/katzen_testimony.pdf].

by directing agencies to justify regulatory actions on the basis of market failure," (2) "unwisely expands OIRA's authority to guidance," (3) "resurrect's the discredited concept of a regulatory budget," and (4) "further politicizes the regulatory process" through the new regulatory policy officer designation process.[39]

- Rick Melberth, director of federal regulatory policy at OMB Watch, recommended that Congress (1) explore the legality of the executive order amendments and their implementation, (2) oversee the issuance of OIRA guidance on the market failure principle, and (3) "look at limiting agencies' and OIRA's spending on the specific elements of the amendments."[40]

The fourth hearing witness, however, welcomed the issuance of E.O. 13422. William L. Kovacs, vice president of the U.S. Chamber of Commerce, said the order was "[f]ar from being radical," and merely instructs federal agencies to (1) state the reason for the regulation, (2) identify the aggregate cost of the regulation to assist the identification of agency priorities, and (3) have an agency regulatory policy officer ensure that these requirements have been followed. He also said the order "corrects the abuse of guidance documents by federal agencies seeking to avoid public participation in the rulemaking process," and that the order and the OMB guidance bulletin "are part of a long effort by Congress and several Administrations to improve the transparency and quality of government data and provide effective parameters to guide the regulatory activities of federal agencies."[41]

Subcommittee on Commercial and Administrative Law

At the Commercial and Administrative Law Subcommittee hearing, Chairman Linda T. Sanchez said she was "concerned that the main thrust of this new Order appears to shift control of the regulatory process from the agencies — the entities that have the most substantive knowledge and experience — to the White House." On the other hand, Ranking Member Chris Cannon said the changes were "useful refinements" to the existing regulatory review process, and could be expected to lead to improved governance.

The first witness was Steven D. Aitken, Acting Administrator of OIRA, who said both the new executive order and the OMB guidance bulletin "share the goal of improving the way that the federal government does business." The bulk of his testimony focused on the guidance provisions; there, he said that only some agency guidance documents would be subject to interagency review, and that many agencies may already be doing what the order requires. Mr. Aitken also said that (1)

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[39] For a copy of Mr. Vladeck's written statement, see [http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/vladeck_testimony.pdf].

[40] For a copy of Mr. Melberth's written statement, see [http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/Melberth_testimony.pdf].

[41] For a copy of Mr. Kovac's written statement, see [http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/kovacs_testimony.pdf].

regulatory policy officers in many federal agencies were already presidential appointees, and that by requiring the designation of presidential appointees for this position the President was ensuring that, in most cases, the initiation of rulemaking would be authorized by individuals in Senate-confirmed positions; (2) the requirement that agencies aggregate the costs and benefits of their upcoming rules shifts the burden of summing up rules from the public to the agencies; and (3) the concept of market failure has always been part of E.O. 12866, is not the only basis on which agencies can justify their regulations, and does not affect other statutory provisions that may prompt the issuance of a rule.[42]

One other witness at the hearing — Paul Noe, of C&M Capitolink, LLC, and former counselor to former OIRA Administrator John Graham — indicated that E.O. 13422 comprised "important and salutary steps toward good governance," and did not represent a threat to federal rulemaking. For example, he said the provisions in the order involving regulatory policy officers "only codifies prior practice in both the Bush and Clinton Administrations," and he characterized the requirement for aggregate cost and benefit estimates as a sensible "toting up of already required information."[43]

Two other witnesses at this hearing were less sanguine about the effects of the executive order. Sally Katzen repeated the concerns that she voiced at the earlier hearing, and concluded by saying that "the message [of the executive order] is that agencies should not be doing the job that Congress has delegated to them."[44] Another witness, Peter Strauss of Columbia Law School, said that the regulatory policy officer provisions in the executive order "threatens a dramatic increase in presidential control over regulatory outcomes, to an extent Congress has not authorized and in my judgement must authorize." He also said that the provisions regarding formal rulemaking "threatens redeployment of a discredited, remarkably expensive rulemaking procedure that delivers substantial controls over the timing and cost of rulemaking into the hands of private parties — notably, I fear, those whose dangerous activities proposed regulations are intended to limit." Professor Strauss, noting that the President could veto any freestanding legislation designed to undo the executive order, suggested that a "do not spend" rider on an appropriations bill was more likely to be effective in preventing the order from taking effect.[45]

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[42] For a copy of Mr. Aitken's written statement, see [http://judiciary.house.gov/media/pdfs/Aitken070213.pdf].

[43] For a copy of Mr. Noe's written statement, see [http://judiciary.house.gov/media/pdfs/Noe070213.pdf].

[44] For a copy of Ms. Katzen's written statement, see [http://judiciary.house.gov/OversightTestimony.aspx?ID=726].

[45] For a copy of Mr. Strauss' written statement, see [http://judiciary.house.gov/media/pdfs/Strauss070213.pdf].

Concluding Notes

The amendments made by E.O. 13422 to E.O. 12866 are the most significant since the latter order was issued in 1993, but the characterizations of the changes by interested parties are dramatically different. Jeffrey Rosen, general counsel at OMB, reportedly characterized the new executive order as "a classic good-government measure that will make federal agencies more open and accountable."[46] On the other hand, Gary Bass, executive director of OMB Watch said the changes made to the regulatory review process were "bad, bad, bad," and predicted that they would hamper the government's ability to respond to regulatory crises such as E.coli outbreaks on fresh vegetables.[47] One Member of Congress was quoted as saying that the order "allows the political staff at the White House to dictate decisions on health and safety issues, even if the government's own impartial experts disagree. This is a terrible way to govern, but great news for special interests."[48]

Although observers have taken very different positions on the desirability of the changes made by E.O. 13422, several things about the order are not clear. First, it is unclear why the changes to the existing regulatory review process were made. Notably, although E.O. 13422 requires agencies to provide written rationales for why they are issuing regulations, no such rationale was offered in conjunction with this or any of the other new requirements in the order. For example, it is unclear what "market failure" or other specific problem led to the issuance of the requirements that agencies have regulatory policy officers who are presidential appointees, or that agencies submit significant guidance documents to OIRA for review. Although the acting OIRA Administrator indicated that the executive order's guidance provisions were intended to "reinforce" the OMB guidance bulletin and improve the quality of agency guidance documents through interagency review, he did not describe any recent instances of poor quality guidance that led to this provision in the order. Also, his comments indicating that other parts of the executive order were consistent with existing practices (e.g., provisions regarding "market failure" and formal rulemaking) raise questions regarding why changes to the executive order were believed necessary. Neither the President nor OMB is required to explain why executive orders are issued, or why existing OIRA review processes are changed. And sound public policy rationales can be envisioned concerning why the changes were made. Providing those rationales might have gone a long way toward quieting some of the concerns that have been voiced regarding the changes.

Also unclear is the effect of the changes made by E.O. 13422 on federal rulemaking agencies, the rules that emerge from the rulemaking process, and on the transparency of that process to the public. In some cases, that lack of clarity is because of the discretion given to agencies and OIRA in the review process (e.g., that agencies take certain actions "to the extent possible" or "where applicable"). In other cases, the effects are unclear because the order does not appear to change existing

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[46] Robert Pear, "Bush Directive Increases Sway on Regulation."

[47] John D. McKinnon, "White House Flexes Muscles Over U.S. Regulations," *Wall Street Journal (Europe)*, Feb. 1, 2007, p. 12.

[48] Robert Pear, "Bush Directive Increases Sway on Regulation."

practices (e.g., that agencies be allowed to use formal rulemaking). In still other cases, the new requirements seem to be based on false presumptions (e.g., that agencies' regulatory plans contain estimates of costs and benefits that can be aggregated) or seem to have an indefinite scope (e.g., what qualifies as a "guidance document" or a "significant guidance document").

Ultimately, the degree to which E.O. 13422 changes existing practices will likely depend on how the order is implemented by OIRA and the agencies. Will, for example, OIRA insist that agencies identify a "specific market failure" before issuing proposed or final rules, or will that provision be interpreted more broadly to require simply a clear statement of the rules' intentions? Will agency heads continue to have discretion in the appointment of regulatory policy officers (albeit less than before since they must now select from current presidential appointees), or will the White House direct the agency heads in those appointments? Will these policy officers continue to report to the agency heads, or will they now report to the White House or OMB? Will the requirement that agencies provide estimates of aggregate costs and benefits be used as a prelude to greater control and the development of regulatory budgets, or will such estimates be relatively easy to develop and reveal cumulative effects that have heretofore been hidden? Will the requirement that OIRA be notified of forthcoming significant agency guidance documents prove to be a major expansion of presidential influence over regulatory agencies, or will "significant guidance document," as defined in the order, be a contradiction in terms resulting in virtually no such documents being covered by the order's requirements? And finally, will OIRA require agencies to enter into more formal rulemaking procedures, or will agencies continue to have the discretion to use such procedures only in rare circumstances?

Third, it is unclear what impact the changes brought about by E.O. 13422 will have on the balance of power between the President and Congress in this area. Congress has a vested interest in the regulations that emerge from the rulemaking process, having created each regulatory agency, confirmed agency heads, and enacted the legislation underpinning each proposed and final rule. Therefore, presidentially initiated changes that may affect these congressional directives (e.g., the requirement that each agency identify a specific "market failure" or "problem" before issuing a rule) are naturally of potential interest to Congress. Another area of the executive order that may affect presidential-congressional balance of power involves the regulatory policy officers, particularly their new authority to control regulatory planning and output (unless the agency head objects), the fact that they no longer report to the agency head, and the lack of clarity as to whether they must be confirmed by the Senate (or reconfirmed because of their new authorities). Finally, it is unclear whether the executive order intended to require that independent regulatory agencies have presidential appointees as regulatory policy officers. Doing so would extend the reach of the President and presidential review into agencies that had not previously been subject to such scrutiny (and commensurately lessening the agencies' relationships with Congress, which created them to be more independent of the President).

These three areas of uncertainty notwithstanding, the issuance of these amendments to E.O. 12866 are important if for no other reason than that the President deemed them necessary. The changes made by E.O. 13422 — particularly

the expansion of OIRA review to guidance documents and the requirement that regulatory policy officers be presidential appointees with enhanced power — represent a clear expansion of presidential authority over rulemaking agencies. In that regard, the executive order can be viewed as part of a broader statement of presidential authority presented throughout the Bush Administration — from declining to provide access to executive branch documents and information to presidential signing statements indicating that certain statutory provisions will be interpreted consistent with the President's view of the "unitary executive."[49] In fact, in his testimony on the order, the acting OIRA Administrator cited the "basic need of the President and his White House staff to monitor the consistency of executive agency regulations with Administration policy" as justification for the extension of OIRA review to agency guidance documents.

OMB indicated that it planned to issue clarifying "implementation assistance" to the agencies, which may answer many, if not all, of these questions. Meanwhile, some Members of Congress and witnesses at the February 2007 hearings on E.O. 13422 suggested that Congress block the implementation of the order through legislation. Congress has revoked executive orders in the past, both directly (e.g., declaring that a specific order shall not have any legal effect) and by reversing certain provisions in the orders.[50] However, if the President chooses to veto such legislation, enactment into law would require a two-thirds majority in both Houses of Congress. Therefore, some (e.g., Professor Peter Strauss) have suggested including language prohibiting the implementation of the executive order in "must pass" legislation (e.g., appropriations bills), thereby making a presidential veto less likely. Whether or not legislation is introduced to block the order's implementation, some form of ongoing congressional oversight of E.O. 13422 is likely.

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[49] For a discussion of the Bush Administration's use of signing statements, see CRS Report RL33667, *Presidential Signing Statements: Constitutional and Institutional Implications*, by T.J. Halstead. More generally, see Adriel Bettelheim, "Executive Authority: A Power Play Challenged," *CQ Weekly*, Oct. 30, 2006, p. 2858. For a discussion of the unitary executive principle, see Christopher S. Yoo, Steven G. Calabresi, Anthony J. Colangelo, "The Unitary Executive in the Modern Era, 1945-2004," 90 *Iowa L. Rev.* 601 (Jan. 2005); and Robert v. Percival, "Presidential Management of the Administrative State: The Not-So Unitary Executive," 51 *Duke Law Journal* 963 (Dec. 2001).

[50] CRS Report RS20846, *Executive Orders: Issuance and Revocation*, by T.J. Halstead. The most recent direct congressional revocation appears to have involved E.O. 12806, an order by President George H.W. Bush to the Secretary of the Department of Health and Human Services to establish a human fetal tissue bank for research purposes. Congress revoked the order by simply stating that "the provisions of Executive Order 12806 shall not have any legal effect." See P.L. 103-43, 107 Stat. 133, 121. For other examples, see House Committee on Rules, Subcommittee on Legislative and Budget Process, 106th Cong., 1st Sess., *Hearing on the Impact of Executive Orders on Lawmaking: Executive Lawmaking?* (Oct. 27, 1999), pp. 124-127.